

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters ) MD-15-02641-PHX-DGC  
Products Liability Litigation )  
 ) Phoenix, Arizona  
 ) March 15, 2018  
 )  
Sherr-Una Booker, an individual, )  
 )  
Plaintiff, )  
 ) CV-16-00474-PHX-DGC  
v. )  
 )  
C.R. Bard, Inc., a New Jersey )  
corporation; and Bard Peripheral )  
Vascular, Inc., an Arizona )  
corporation, )  
 )  
Defendant. )

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 2 A.M. SESSION

(Pages 216 - 336)

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Proceedings Reported by Stenographic Court Reporter  
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**P R O C E E D I N G S**

(Proceedings resumed in open court outside the presence of the jury.)

THE COURT: Please be seated.

All right. Good morning, everybody.

MR. LOPEZ: Good morning, Your Honor.

MR. NORTH: Morning.

THE COURT: Counsel, do you have matters you want to raise before we start this morning?

MR. LOPEZ: I don't think so, Your Honor. I think maybe the defense wants to talk about the idea of us providing them with exhibits before witnesses. And you suggest that might be a good idea, but we would prefer not to do that, Judge. I mean, I still think that's work product. If, for example, when we take depositions in this case and we ask for exhibits or documents that they've used with their witnesses to prepare the witness or to refresh their recollection, they maintain a work product privilege to that, because that is a lawyer's impressions on information that may or may not be important. We think that is the same here.

More importantly, I mean, this is -- sometimes we don't decide until 2:00 in the morning what documents we may or may not use. And this is a dynamic situation. We would prefer not to have to do that, because, for the most part,

08:31:44 1 these witnesses that are being deposed -- that are testifying  
2 in court, the documents -- 90-plus percent of the documents  
3 we're going to be using have been used in the deposition. So  
4 it's not like there's any surprises or any disadvantage or  
08:31:59 5 anything like that.

6 Bottom line is we want to maintain our work product  
7 privilege to our impressions about what documents we think  
8 might be important for a particular witness.

9 MR. NORTH: Your Honor, our recollection is at the  
08:32:13 10 pretrial conference, the Court said it might be a good idea to  
11 facilitate matters if the parties disclose 24 hours in advance  
12 of a witness or the testimony as to what exhibits they were  
13 going to use. We obviously recognize there are last minute  
14 changes, and you can't give an ironclad disclosure.

08:32:34 15 We asked Mr. Lopez yesterday if he would advise us as  
16 to the documents that would be used today generally within --  
17 again, understanding there might be additions. He recognized  
18 that the Court had suggested it was a good idea. Told us,  
19 though, he would not do it because he considered it work  
08:32:53 20 product.

21 I'm not sure I understand the basis of the work  
22 product claim, particularly when you're 24 hours away from  
23 putting a witness on. It's just a matter of trial logistics.  
24 I think it would help both sides to facilitate the matter to  
08:33:06 25 have as much advanced notice as possible as to the exhibits

08:33:10 1 being used to prevent us from scrambling. So I don't know if  
2 that is something the Court is willing to enter an order on,  
3 or if it's just sort of an aspirational thing for the parties.

4 THE COURT: What kind of access do you have to  
08:33:24 5 exhibits, Mr. North?

6 MR. NORTH: I'm sorry, Your Honor, what kind of  
7 access?

8 THE COURT: Yeah. Do you have them on your computer  
9 or --

08:33:34 10 MR. NORTH: Yes. We have thumb drives with them on.  
11 We had some difficulty last night determining how to identify  
12 the exhibits. My understanding is that that's been worked out  
13 this morning. But we do have the exhibits electronically.

14 THE COURT: My view on this issue is that you should  
08:34:18 15 provide them 24 hours in advance.

16 I understand your argument, Mr. Lopez, but I think at  
17 this stage, when we're in trial, when the issues have been  
18 squarely framed, when witnesses and documents have been  
19 identified, motions in limine have been ruled upon, there are  
08:34:35 20 few secrets between you on trial strategy, and that the  
21 convenience to each side of knowing generally what documents  
22 are going to be used a day in advance will move the trial  
23 along.

24 That doesn't mean it's an ironclad disclosure. I  
08:34:49 25 mean, if you decide at 2:00 in the morning you want to use

08:34:53 1 five documents you didn't disclose, you can do that. I'm not  
2 going to say you're precluded from adding to the list or  
3 subtracting from the list. I think it's a good faith effort  
4 on each side to identify the documents. I'm guessing  
08:35:05 5 95 percent of the documents that will be shown to witnesses  
6 are matters that were shown to them in their depositions.  
7 It's not a surprise.

8 So it's aspirational. It's not going to be a  
9 preclusion if you fail to make a disclosure. But let's make  
08:35:20 10 our best efforts to tell each side 24 hours in advance what  
11 documents will be used. And I think that will move things  
12 along a little more quickly during the trial.

13 Are there other matters you all want to raise?

14 MR. NORTH: Nothing for the defense, Your Honor.

08:35:36 15 MR. CONDO: I'm sorry. Your Honor, two points.  
16 Number one, we talked about this during the pretrial. There  
17 are going to be some witnesses we thought we would put on our  
18 direct at the times they were called by the plaintiff,  
19 Mr. Chanduszko is one of those. There are a number of  
08:35:59 20 subjects that were raised yesterday that would be part of the  
21 direct in any event, so I would intend to do my direct of  
22 Mr. Chanduszko so he can be released, and do it as part of the  
23 cross-examination.

24 THE COURT: How long do you think that would take,  
08:36:16 25 Mr. Condo?



08:36:16 1 MR. CONDO: Well, we've got 40 --

2 THE COURT: The direct part of your examination.

3 MR. CONDO: The direct part, probably about 40  
4 minutes.

08:36:30 5 MR. O'CONNOR: That's the problem, Your Honor,  
6 because we've got experts that are coming into town. We've  
7 got people scheduled tight to comply with this and, you know,  
8 they haven't given us -- they did give us documents yesterday  
9 for Chanduszko, but they listed him separately in their  
08:36:49 10 witnesses.

11 He's here in Phoenix, and we don't see any reason  
12 that our case should be taken off track, especially since we  
13 have people from out of town that are going to be put on today  
14 and this evening. We've got experts coming in tonight and  
08:37:07 15 tomorrow.

16 THE COURT: Mr. Condo, is Mr. Chanduszko located in  
17 town?

18 MR. CONDO: He is, sir.

19 THE COURT: My concern when we talked about that was  
08:37:16 20 more for out-of-state folks who are brought in, to get them on  
21 and off. I think if he can drive over from Tempe for your  
22 direct, we ought to have him do that and allow plaintiffs to  
23 stay on schedule with their witnesses. So let's hold the  
24 direct until your case.

08:37:30 25 MR. CONDO: I will try to do that, but some of what I

08:37:32 1 wanted to --

2 THE COURT: Clearly there will be overlap, I know.

3 MR. CONDO: Okay. Some of what I wanted to address  
4 will. For example, they talked about fatigue testing. I  
08:37:41 5 would like to introduce some of the fatigue tests that were  
6 done.

7 THE COURT: I think that's within the scope of  
8 cross-examination.

9 MR. CONDO: Yeah.

08:37:49 10 THE COURT: That's a topic they've clearly asked  
11 about.

12 MR. CONDO: Thank you.

13 THE COURT: Okay.

14 MR. O'CONNOR: Except, you know, I don't want to be  
08:37:56 15 standing up and interfering. The question was a very limited  
16 question. We didn't go into --

17 THE COURT: You can object at the time. But if I  
18 think it's within the scope, I'm going to allow it, even if it  
19 involves putting another exhibit in if it is fairly within the  
08:38:07 20 scope of what you covered.

21 All right. Are there other matters we need to take  
22 up?

23 MR. O'CONNOR: I would just ask, Your Honor, if in  
24 fact we do go through the courtesy of trying to give exhibits,  
08:38:22 25 that we could have some objections in advance so we're not

08:38:25 1       wasting time with a witness.

2               THE COURT:  Objections?  How do we do that?

3               MR. O'CONNOR:  If they're going to object to us using  
4       an exhibit for a witness after we provide it to them, we would  
08:38:36 5       like them to give that to us before we put the witness on if  
6       we give them the exhibits in advance.

7               MR. NORTH:  Your Honor, I think that's impossible to  
8       do in a vacuum.  I mean, an exhibit may be nonobjectionable  
9       depending on how it is used with a witness.

08:38:49 10              THE COURT:  I don't think we ought to try to exchange  
11       objections ahead of time.  It will be the same for both sides.  
12       You'll get the exhibits ahead of time.  You can decide to  
13       object.  But I can't rule on an objection until I have a  
14       witness on with a document in front of him.  So we're going to  
08:39:05 15       exchange exhibits, but not objections.

16              Anything else we need to address?

17              MR. CONDO:  Your Honor, just one personal item.  I am  
18       getting over a cold and some bronchitis, and I am sucking on  
19       cough drops.  I don't mean to be disrespectful to the Court or  
08:39:24 20       to the jury, but from time to time I may be up there  
21       unwrapping one and --

22              THE COURT:  That's fine.

23              MR. O'CONNOR:  Now we know why Mr. Nations isn't  
24       feeling well.

08:39:37 25              THE COURT:  Is he the follow who got sick?

08:39:39 1 MR. LOPEZ: Yes.

2 THE COURT: How is he doing?

3 MR. LOPEZ: I think he's out of bed. He may show up  
4 and sit in the back.

08:39:50 5 THE COURT: The other thing I wanted to mention is I  
6 would like, if I can find the time, to review my ruling on  
7 expert motions in limine before experts get on the stand so at  
8 least what I said was fresh.

9 So the question I have for plaintiffs is when do you  
08:40:05 10 think your first expert will be on and who that will be?

11 MR. O'CONNOR: We could start as early as this  
12 afternoon with Dr. McMeeking.

13 THE COURT: McMeeking will be first?

14 MR. O'CONNOR: Yes.

08:40:15 15 THE COURT: Do you anticipate getting to any other  
16 experts today?

17 MR. O'CONNOR: No. And then tomorrow, assuming  
18 McMeeking carries over, then there will be Dr. Michael  
19 Streiff.

08:40:22 20 THE COURT: All right. So McMeeking today, Streiff  
21 tomorrow.

22 Any others you expect tomorrow?

23 MR. LOPEZ: None, Your Honor.

24 MR. O'CONNOR: No.

08:40:30 25 THE COURT: Okay. That will help me to try to do

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

08:40:32 1 that review, if I can.

2 Okay. We will bring the jury in at 9 o'clock, and  
3 I'll come in when they're ready.

4 (Recess was taken from 8:40 to 9:00. Proceedings resumed  
08:40:50 5 in open court with the jury present.)

6 THE COURT: Thank you. Please be seated.

7 Good morning, ladies and gentlemen. Thank you for  
8 being here this morning.

9 We're going to pick up where we left off yesterday.

09:01:10 10 Mr. Chanduszko, you can come back to the witness  
11 stand.

12 And, Mr. O'Connor, you may proceed.

13 MR. O'CONNOR: Thank you, Your Honor.

14 ANDRE CHANDUSZKO,

09:01:15 15 recalled as a witness herein, after having been previously  
16 sworn or affirmed, was examined and testified as follows:

17 D I R E C T E X A M I N A T I O N (CONTINUED)

18 BY MR. O'CONNOR:

19 Q Good morning, Mr. Chanduszko.

09:01:46 20 A Good morning.

21 Q Thank you for coming back.

22 Let's resume where we were yesterday. We talked  
23 about environment of use, and specifically vena cava dynamics  
24 in the context of distention. Do you remember that  
09:02:05 25 discussion?

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:02:06 1 A Yes, I do.

2 Q And, again, for the jury, distention means the expansion  
3 of the vena cava; correct?

4 A That's correct.

09:02:15 5 Q And that is the anatomy that a company should be aware if  
6 they're going to manufacture a device that will be implanted  
7 in the vena cava. True?

8 A Yes, they should be aware.

9 Q Were you aware, Mr. Chanduszko, that Bard did not do any  
09:02:34 10 bench testing for distention on the Recovery filter before it  
11 went to market?

12 A That's correct. My understanding is that NMT did all the  
13 testing.

14 Q No, but are you aware there was no bench testing, period,  
09:02:50 15 on distention before the Recovery went to market?

16 A In general, that's -- that's probably correct.

17 Q So just so you and I are on the same page, there was no  
18 testing for distention before the Recovery went on the market.  
19 True?

09:03:10 20 A So I can't say categorically because the filter is tested  
21 in different sizes of cava. So if the distended size is  
22 within the test range, the test would automatically account  
23 for this.

24 Q I'm going to show you Exhibit 2066.

09:03:40 25 You know who Mr. McDermott is?

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09:03:43 1 A Yes, I do.

2 THE WITNESS: I'm sorry, I think the cup is leaking.

3 THE COURTROOM DEPUTY: Oh. I'll get it.

4 I'll get you some paper towels.

09:04:12 5 THE WITNESS: Sorry about this.

6 BY MR. O'CONNOR:

7 Q You know who Mr. McDermott is; is that correct?

8 A Yes, I do.

9 Q And you see that this is an e-mail from -- excuse me,

09:04:23 10 Len DeCant, do you recall who he is at Bard?

11 A Yes. He was vice president of R&D at that time.

12 Q And as you look through this e-mail exchange, it talks  
13 about the issue of distention.

14 A So they use the word in the first sentence, yes.

09:04:45 15 Q And go to the second page, please.

16 MR. CONDO: 602.

17 THE COURT: Well, there isn't a question pending yet.

18 MR. CONDO: I'm just --

19 BY MR. O'CONNOR:

09:04:58 20 Q So you see there --

21 THE COURT: Hold on just a minute. Hold on just a  
22 minute.

23 MR. CONDO: I think they're going to be asking  
24 questions about the content of the document.

09:05:08 25 THE COURT: Okay. Let's see what the question is and

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:05:10 1 you can certainly object again.

2 BY MR. O'CONNOR:

3 Q You see there that Mr. McDermott asked the question to Len  
4 to, Please make sure we're doing some kind of testing to  
09:05:19 5 determine distensibility of cavas. And that is on July 26,  
6 2004.

7 MR. CONDO: Your Honor, that's the basis of the  
8 objection. Reading from a document that's not admitted into  
9 evidence.

09:05:31 10 THE COURT: Sustained. It's not in evidence.

11 MR. O'CONNOR: Well, at this time I would move it in  
12 evidence, Your Honor.

13 MR. CONDO: Can we have the foundation, Your Honor?  
14 I would object.

09:05:39 15 THE COURT: Sustained without foundation.

16 BY MR. O'CONNOR:

17 Q Is it your testimony that Bard was not aware -- did not do  
18 any distention testing before the Recovery went to market?

19 A That would be my understanding.

09:05:52 20 Q So you agree with that?

21 A So I was not at Bard at the time. So I can't say I have  
22 any particular knowledge that that was something done in that  
23 area.

24 Q If the evidence shows there was no testing of distention  
09:06:09 25 before the Recovery went to market, you would not disagree



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09:06:13 1 with that; correct?

2 A I'm not sure lack of evidence prove that there was nothing  
3 done, but I can certainly say that I'm not aware of any  
4 particular evidence of that testing.

09:06:34 5 Q Now, even after the G2 was released, or before the G2 was  
6 released, there was no testing or thorough understanding of  
7 the dynamics of the vena cava. Do you agree with that?

8 Bard did not have a thorough understanding of the  
9 vena cava dynamics, including distention, before the G2 was  
09:06:57 10 released.

11 A I'm not sure if the word "thorough" fully describes it.  
12 We had -- or Bard, according to my knowledge, had an  
13 up-to-date understanding of what the cava can do.

14 Q Would you be surprised if there was a document dated  
09:07:18 15 May 6, 2008, from Bard that indicated that Bard had a lack of  
16 thorough understanding of dynamics of the caval anatomy which  
17 impacted test methods?

18 MR. CONDO: Same objection.

19 THE COURT: Which is?

09:07:34 20 MR. CONDO: 602. Foundation.

21 THE COURT: Sustained.

22 BY MR. O'CONNOR:

23 Q Would you be surprised that Bard was unaware and did not  
24 have a thorough understanding as of May 2008 of vena cava  
09:07:45 25 dynamics?

DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:07:49 1 A So without seeing the document and without knowing  
2 actually what was said, I can't really make a comment on this.

3 Q Now let's go to Exhibit Number 932.

4 This is -- I'm showing you a Bard Peripheral Vascular  
09:08:15 5 document filter franchise review. Do you see that?

6 A Yes.

7 Q And it is a document from Bard. Do you see that?

8 A Yes, that's correct.

9 Q It's dated May 6, 2008. Do you see that?

09:08:25 10 A Yes.

11 Q And if you go to 867, do you know what SWOT was?

12 You were aware that Bard had objectives to increase  
13 revenue and capture more of the market share when it was  
14 marketing filters?

09:08:50 15 MR. CONDO: Objection. 602. Reading from the  
16 document not in evidence.

17 THE COURT: I don't think that question was reading  
18 from the document, it was just asking him. So overruled.

19 Sir, you're to just answer from your own memory, not  
09:09:02 20 from the document.

21 THE WITNESS: So I was not involved directly in any  
22 of these activities, so I can't really comment on that detail.

23 MR. O'CONNOR: Okay. But you can see in a Bard  
24 document that there was a statement by Bard?

09:09:18 25 MR. CONDO: 602.

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:09:20 1 THE COURT: Sustained.

2 BY MR. O'CONNOR:

3 Q Well, this is a Bard document; correct? And you were  
4 employed at Bard on May 6, 2008; correct?

09:09:34 5 A It's a Bard document and yes, I was an employee of Bard at  
6 that time.

7 Q You were involved in the G2 filter program; correct?

8 A Yes, as an engineer.

9 Q All right. And what was important to engineers was the  
09:09:49 10 knowledge, what Bard's understanding of vena cava dynamics  
11 was. True?

12 A Yes, that's true.

13 Q And do you agree that Bard did not have a thorough  
14 understanding of vena cava dynamics as of May 6, 2008, after  
09:10:06 15 the G2 was released to market?

16 A So I read that Bard knew lots of things about vena cava,  
17 but also I cannot say that we knew everything.

18 Q And do you agree there was no testing at that time for  
19 distensibility as it relates to the G2 that was done before  
09:10:31 20 the G2 was released?

21 A So --

22 Q Do you agree with that or not?

23 A So the testing, the filter design certainly addressed that  
24 issue and I believe there was some testing done to it as well.  
09:10:52 25 So it was addressed in two different ways.

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

Q If there is a Bard document that says that Bard did not have a thorough understanding of vena cava anatomy that impacted test methods, would you disagree with that?

A So, again, I think if that means that --

Q Sir, would you disagree if there is a Bard document out there that indicates that Bard lacked a thorough understanding of dynamics of caval anatomy?

MR. CONDO: Objection. 602 again.

THE COURT: I think you ought to ask the question directly, Mr. O'Connor. You're asking him if he disagrees with a document he hasn't seen.

BY MR. O'CONNOR:

Q Do you disagree that Bard lacked a thorough understanding of the dynamics of caval anatomy, that impacted test methods?

A At what time?

Q After the G2 was released, as of May 6, 2008.

A So as I said, we obviously don't know everything, but based on my knowledge, we had a sufficient understanding and testing to address that.

MR. O'CONNOR: Your Honor, I move to admit the document May 6, 2008.

THE COURT: What is the exhibit number?

MR. O'CONNOR: Excuse me. 932.

MR. CONDO: We would object.

THE COURT: Basis?

DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:12:25 1 MR. CONDO: No foundation. 602.

2 THE COURT: 602 is not a basis for objecting to  
3 admission of a document?

4 MR. CONDO: There is no foundation that this witness  
09:12:32 5 has seen this document.

6 THE COURT: He doesn't have to have for a document to  
7 be admitted.

8 MR. CONDO: It's also a draft document, not the final  
9 document.

09:12:41 10 THE COURT: I don't think that's a valid basis  
11 either, so I'm going to overrule those objections and admit  
12 932.

13 (Exhibit 932 admitted.)

14 MR. O'CONNOR: May I publish this to the witness and  
09:12:50 15 the jury, Your Honor?

16 THE COURT: You may.

17 MR. O'CONNOR: Let's go to the first page of 932.

18 The first page, Greg.

19 BY MR. O'CONNOR:

09:13:06 20 Q What I'm showing you is Exhibit 932, and it is a document  
21 entitled "Bard Peripheral Vascular Filter Franchise Review."

22 Do you see that?

23 A Yes, I do.

24 Q And that document is dated May 6, 2008.

09:13:21 25 Do you see that?

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09:13:22 1 A Correct.

2 Q And the G2 filter was released to the market in 2005;  
3 correct?

4 A I don't have an exact recollection, but, yes, roughly  
09:13:36 5 around that time.

6 Q All right. And if we go to Bates 867 --

7 MR. O'CONNOR: Will you go there, Greg.

8 And, Greg, can you call out the Weaknesses section of  
9 this SWOT document, increased revenue and capture more market  
09:13:56 10 share.

11 BY MR. O'CONNOR:

12 Q And, sir, do you see where this document that's been  
13 produced by Bard states "Weaknesses." Under the term  
14 "Weaknesses," "Lack of full understanding dynamics caval  
09:14:09 15 anatomy impacting testing methods."

16 Did I read that correctly?

17 A Yes.

18 Q The document goes on to state that Bard: We have a  
19 historical reactive/evolution design mindset.

09:14:31 20 Did I read that correctly?

21 A Yes, that's correct.

22 Q It goes on to say: Product complications-forcing focus on  
23 reactive designing.

24 Did I read that correctly?

09:14:45 25 A Yes.

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

Q And yesterday when we talked about the responsibility to understand user needs as of May 6, 2008, Bard stated in this Exhibit 932 that there was a limited understanding of user needs.

Did I read that correctly?

A Yes, sir, you did.

Q And that is almost three years after the filter was released for patients in the market; correct?

A If '05 is correct, then yes.

Q Do you agree before putting the G2 on the market that there was no caudal migration test on the G2 that was done at Bard?

A Before putting G2 on the market?

Q Yes.

A No, I don't agree.

Q So you -- it's your position today that there was caudal migration testing of the G2 before it was released in 2005?

A Yes. That was one of the aspects that was evaluated.

Q Okay. So if there is a statement by Bard that indicates otherwise, you would disagree with that statement?

A Probably. I have to see the statement.

MR. O'CONNOR: Greg, put up 4327.

THE COURTROOM DEPUTY: Hang on for a second.

MR. O'CONNOR: Exhibit 4327.

Do you have -- is it up?

DIRECT EXAMINATION - ANDRE CHANDUSZKO

MR. WOODY: Page what?

MR. O'CONNOR: Just the first page so I can introduce it.

BY MR. O'CONNOR:

Q We're looking at Exhibit 2347. Mr. Chanduszeko, you see that this is a memorandum to Tim Ring and John Weiland from John McDermott dated February 10, 2006?

Do you see that?

A That's correct.

Q And who are Mr. Ring and Mr. Weiland? They're pretty important people at Bard; right?

A Yes. President and CEO of Bard.

Q And John McDermott, he was a vice president; right?

A He was the president of our division.

Q Your division is Bard Peripheral Vascular?

A Yes, that's correct.

Q So Mr. McDermott was a very important man at this time.

A Yes, of course.

Q Somebody that you understood made it his business to know about Bard products and how they were doing on the market?

A Yes, that would be my understanding.

Q All right.

MR. O'CONNOR: Greg, please go to 19 -- excuse me, 9573, the Bates number.



DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:18:01 1 BY MR. O'CONNOR:

2 Q Do you see this page that's entitled "Product  
3 Development/Launch Schedule"?

4 A Yes, I do.

09:18:19 5 Q And there's discussions about the G2 and caudal  
6 improvements. Do you see that?

7 A Yes, I do.

8 MR. O'CONNOR: Your Honor, at this time I move to  
9 admit Exhibit 4327.

09:18:34 10 MR. CONDO: 802, Your Honor.

11 THE COURT: Sustained.

12 BY MR. O'CONNOR:

13 Q Well, if there is -- if Bard contended that it was  
14 developing a team to test -- it was developing a test method  
09:18:58 15 for evaluating caudal migration resistance as of February 10,  
16 2006, do you have any reason to disagree with that?

17 A No, I don't --

18 THE COURT: Hold on, sir.

19 What's the objection?

09:19:12 20 MR. CONDO: 802 and 602.

21 THE COURT: Sustained. The document's not in  
22 evidence.

23 BY MR. O'CONNOR:

24 Q I'm asking you, would you disagree if Bard was still  
09:19:22 25 developing or was developing a test for -- a test method for

DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:19:26 1 caudal migration in February of 2006 for the G2?

2 A Yes, so it looks like --

3 THE COURT: Excuse me, sir. The question is not  
4 about the document because it's not in evidence. He's asking  
09:19:37 5 about your knowledge.

6 Would you re-ask the question, Mr. O'Connor.

7 MR. O'CONNOR: Sure.

8 BY MR. O'CONNOR:

9 Q If Bard was developing a test method for evaluating caudal  
09:19:51 10 migration resistance of the G2 after it was released around  
11 the time period of February 2006, would you disagree with  
12 that?

13 A No, I wouldn't.

14 Q And were you aware that Bard had caudal migration failure  
09:20:12 15 investigations under way to determine the design or the issues  
16 relating to design and physiological causes of caudal  
17 migration?

18 A Yes, I was aware of an investigation.

19 Q All right. So is it fair to say that Bard had not tested  
09:20:32 20 the G2 for caudal migration before it was released to the  
21 market?

22 A That wouldn't be my understanding.

23 Q Pardon me?

24 A That would not be my understanding.

09:20:43 25 Q All right.

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:20:43 1 MR. O'CONNOR: Then I move to admit 4327, which  
2 states something on that issue.

3 MR. CONDO: 802.

4 THE COURT: Sustained.

09:20:53 5 MR. O'CONNOR: Well, Your Honor, this is --  
6 BY MR. O'CONNOR:

7 Q This is a document from Bard; correct?

8 A This one?

9 Q Yes.

09:21:01 10 A Yes, that's correct.

11 Q And it's a document that was developed by Bard through its  
12 president of Bard Peripheral Vascular; correct?

13 A I'm not sure that that's the case. Just looking at the  
14 document.

09:21:13 15 Q Well, on the first page, do you have any reason to  
16 disagree this is a Bard document?

17 A It is Bard document, yes.

18 Q And, sir, that was a document prepared by the vice  
19 president, and it contains on it a product development and  
09:21:30 20 launch schedule; correct?

21 A So I can't really say that he prepared that document.

22 Q Well, do you have any reason to dispute it's a Bard  
23 document?

24 A No. But you asked a different question.

09:21:43 25 Q Do you have any reason to dispute this was a document by

DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:21:46 1 Bard?

2 A No, I don't.

3 Q And so just so we're clear, as of 2006, Bard had been  
4 released to the market; correct? Bard had -- the G2 had  
09:21:57 5 already been on the market. True?

6 A In 2006?

7 Q Yes, sir.

8 A I think it was, but I'm not hundred percent sure.

9 Q And as of 2006, there were still -- there were tests being  
09:22:12 10 developed to evaluate and test caudal migration of the G2.  
11 True?

12 A True.

13 Q And that was after the filter had already been implanted  
14 in patients; correct?

09:22:30 15 A That is correct.

16 Q Let's go to -- you were a member of the G2 design team as  
17 of May 18, 2006; correct?

18 A Yes.

19 Q And at that time -- and -- and you --

09:23:26 20 A So, I'm sorry, if the filter was already released, then I  
21 wasn't.

22 Q Well, you were still an engineer at Bard; correct?

23 A Yes, that's correct.

24 Q And you were still receiving communications from other  
09:23:37 25 people in Bard. True?

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:23:40 1 A True.

2 Q And at that time Bard had realized that they'd had  
3 problems with caudal migration in the G2 filter; correct?

4 A So, yes, we had reports of caudal migrations and, yes,  
09:23:54 5 there was an investigation into the cause, is my recollection.

6 Q And that by that time the filter had been implanted in  
7 hundreds of patients; right?

8 A That would be my best guess, yes.

9 Q And Bard was receiving complaints that the filter was  
09:24:10 10 caudally migrating; correct?

11 A Yes.

12 Q And Bard was receiving complaints that not only was the  
13 filter caudally migrating, but it was also tilting and  
14 perforating through the vena cava; correct?

09:24:24 15 A Yes, there were some complaints like that.

16 Q And there were complaints that it migrated, tilted,  
17 perforated, and fractured; right?

18 A I don't know if it was all the same time, but, yes, these  
19 were complaints I'm aware of.

09:24:40 20 Q And Bard, after the filter was released, the G2 was  
21 released, started to deal with, after the release, the issue  
22 of caudal migration; correct?

23 A As it pertains specifically to the G2 filter, yes.

24 Q And Bard was aware of designs that could prevent or  
09:25:03 25 minimize caudal migration even before the filter was released.

DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:25:07 1 True?

2 A So I'm not sure if that's the case. I mean, as a general  
3 rule, the filter's designed to be stable in the vena cava.

4 Q But --

09:25:26 5 A And it's different for every filter.

6 Q The G2 filter was migrating downward; right?

7 A Yes, some of them.

8 Q And that was a problem that Bard started to address after  
9 the filter was released to the market, the G2; correct?

09:25:45 10 A As a particular response to the medical reports, yes, but  
11 caudal migration is always consideration on design too.

12 MR. O'CONNOR: Move to strike that response.

13 THE COURT: Denied.

14 BY MR. O'CONNOR:

09:26:05 15 Q Well, Mr. Chanduszeko, let's take a look at 544.

16 This was an e-mail from Natalie Wong of Bard. You  
17 know who she was; correct?

18 A Yes, I do.

19 Q And it's dated May 18, 2006, and it's included to a number  
09:26:40 20 of members of Bard, including yourself. Do you see that?

21 A No, I don't.

22 Q Look at --

23 MR. LOPEZ: Hold on.

24 THE COURT: It's not on the screen.

09:26:50 25 MR. O'CONNOR: 2249, I'm sorry. Let's get that up on

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:26:51 1 the --

2 MS. REED ZAIC: Mark, it's not up yet.

3 MR. WOODY: Which one?

4 MR. O'CONNOR: 2249. I apologize.

09:27:02 5 BY MR. O'CONNOR:

6 Q This is an e-mail from Natalie Wong that's addressed to  
7 recipients including you; correct?

8 A Yes, that's correct.

9 Q And it's entitled G2 Caudal Report of 5/8/2006. True?

09:27:17 10 A Actually, no, that's not the title.

11 Q It has that attachment. The subject is "Caudal  
12 Investigation"; right?

13 A That is correct.

14 Q As of May, you were aware of the investigation going on  
09:27:29 15 about caudal migration in the G2 filter; correct?

16 A I'm not sure of the exact timing, but, yes, roughly around  
17 that time.

18 Q Well, according to this document, you at least were  
19 notified in -- with this e-mail and were aware as of the date  
09:27:45 20 of this e-mail about the caudal investigation that was going  
21 on as of May 18, 2006; correct?

22 A So it's a limited information I can see, but it sounds  
23 about right.

24 Q And there it was discussions at that time what could you  
09:28:03 25 do at Bard to prevent or reduce caudal migration; correct?

DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:28:10 1 A As it pertains to G2 filter, yes.

2 Q And at that time there were discussion about putting  
3 caudal anchors on filters that would stop or prevent caudal  
4 migration, filters from going down. True?

09:28:25 5 A So I don't remember any specific activities, but it's  
6 possible.

7 Q All right. Well, let's go to page 924 to refresh your  
8 recollection. This is the attachment that was on the e-mail  
9 that is marked as Exhibit 2249.

09:28:48 10 All right. And you see that is an attachment to the  
11 e-mail and you are a recipient.

12 Do you see that?

13 A So I assume that's the attachment, and, yes, I'm a  
14 recipient.

09:29:01 15 Q And at that time the subject was "Preproduct Assessment  
16 Team Minutes - Caudal Migration."

17 Do you see that?

18 A Yes, I do.

19 Q And it refers to a meeting that occurred on April 28,  
09:29:14 20 2006.

21 MR. CONDO: Could we have the document admitted,  
22 please?

23 THE COURT: Objection sustained. It's not in  
24 evidence.

09:29:19 25 MR. O'CONNOR: But I move to admit it now,



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1 Your Honor, to refresh his recollection, among other things.

2 MR. CONDO: No objection.

3 THE COURT: All right. 2249 is admitted.

4 (Exhibit 2249 admitted.)

5 BY MR. O'CONNOR:

6 Q You see there was a meeting held on April 28, 2006?

7 A Yes, I do.

8 Q And do you recall that meeting as you sit here?

9 A No, I don't.

10 Q Let's scroll down and see what was discussed at that time.

11 THE COURT: Do you want this displayed to the jury,  
12 Mr. O'Connor?

13 MR. O'CONNOR: Please, Your Honor.

14 THE COURT: All right.

15 MR. O'CONNOR: Move to admit 2249 and ask it be  
16 published to the jury.

17 THE COURT: It is already admitted, but if you want  
18 it displayed, please ask for that separately.

19 MR. O'CONNOR: Thank you, I will.

20 BY MR. O'CONNOR:

21 Q At your meeting there was an event reporting data slide.  
22 Do you remember that?

23 A No, I don't.

24 Q But according to this document, that happened at your  
25 meeting in April of 2006; right?

DIRECT EXAMINATION - ANDRE CHANDUSZKO

1 A So it looks like an action item. I don't know if that  
2 was --

3 Q Well, sir, according to this memo there was a discussion  
4 about the Greenfield caudal migration situation and how it was  
5 dealt.

6 Do you see that?

7 A Yes.

8 Q And Greenfield was a filter that was out even before the  
9 G2. Fair?

10 A It was -- I'm sorry?

11 Q It was a retrievable filter that was out even before the  
12 G2. True?

13 A That is not correct.

14 Q Well, was it obviously out before April 28, 2006?

15 A The filter was, but it was not retrievable.

16 Q Okay. But there was a caudal migration issue with the  
17 Greenfield; correct?

18 A Yes, that's what it looks like.

19 Q And according to this document, the way Greenfield dealt  
20 with that issue was redesigning it by flipping two hooks to  
21 prevent caudal migration.

22 Do you see that? Did I read that correctly?

23 A Yes, I do.

24 Q And that was a design that you were aware of that could  
25 address the caudal migration issue. Fair?

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:31:50 1 A Looking at this, yes.

2 Q Pardon me?

3 A So it --

4 Q Is that a design that you were aware of that could reduce  
09:31:57 5 or minimize caudal migration, flipping two hooks to prevent  
6 caudal migration?

7 A For the Greenfield filter, yes.

8 Q And it was something that was done on later versions of  
9 filters at Bard. True? Caudal anchors?

09:32:16 10 A Yes, but that's a completely different solution, so it was  
11 not Greenfield solution.

12 Q But the point is, sir, you were meeting on the G2 filter  
13 and you were addressing a problem of caudal migration;  
14 correct?

09:32:28 15 A That is correct.

16 Q And the first time that was ever addressed by Bard was  
17 after the G2 was released to the market; correct? Caudal  
18 migration.

19 A I don't think that's correct.

09:32:41 20 Q Are you saying there were tests that were done before the  
21 filter was released that dealt with caudal migration?

22 A No. What I'm saying is this is not a test. This is just  
23 looking at -- it's a part of investigation looking at  
24 different filters that had similar issue, but obviously they  
09:33:01 25 were different designs.

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

Q Well, I'm asking you a different question. After the G2 filter was released to the market, the people at Bard became aware that it was experiencing caudal migration. True?

A Yes, that's true.

Q And you knew as an engineer that caudal migration was problematic for a filter that was intended to stop blood clots; correct?

A So I'm not sure if we knew it was problematic for clot trapping. We knew it was undesirable.

Q It was a problem for a patient. Fair?

A It could be.

Q And you were aware that Bard had looked at -- was receiving complaints and was looking at a number of complications it was aware of that dealt with caudal migration; correct?

A Yes. After the filter was released on the market.

Q So the filter was released, there was caudal migration, you were getting complaints from patients and doctors, and Bard starts to investigate at that time. True?

A That's about right, yes.

Q And what you learned was that caudal migration could lead to other complications; correct?

A Possibly, yes.

Q You were aware and Bard was aware that caudal migration could lead to tilting; correct?

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:34:37 1 A So I'm not sure that's exactly the case, but, yes, one  
2 thing I can say is that some of the filters that migrated  
3 caudally had tilt as well.

4 Q And tilt was another issue that Bard was dealing with with  
09:34:53 5 the G2 filter; correct?

6 A Well, yes. We certainly didn't want to have any tilt.

7 Q And tilt in the G2, Bard was aware, could lead to  
8 additional problems, including perforation of the vena cava;  
9 right?

09:35:12 10 A So I'm not sure that we knew for a fact that that was the  
11 case.

12 Q But certainly those -- that was what was being  
13 investigated; right? Bard was aware of tilting, Bard was  
14 aware of perforation, and Bard became aware of fracture of the  
09:35:28 15 G2 filter after it was put on the market; correct?

16 A Yes, that's correct.

17 Q And then when Bard started getting those complaints, Bard  
18 had started having investigations and meetings as to whether  
19 there were relationships between those complications. True?

09:35:44 20 MR. CONDO: 403, Your Honor.

21 THE COURT: Overruled.

22 THE WITNESS: So I'm not sure whether that was  
23 exactly the -- among other things that we looked at, we also  
24 tried to figure out whether there was some association with  
09:36:04 25 different complications.

DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:36:06 1 BY MR. O'CONNOR:

2 Q So you were looking at associations between complications  
3 which included migration, included tilt, included perforation,  
4 included fracture; correct?

09:36:16 5 A That's correct. Among other things with it, yes.

6 Q And those investigations started after you receiving --  
7 received complaints from patients and doctors. True?

8 A Yes, that's true.

9 Q And as the complaints came, Bard continued to sell the G2  
09:36:33 10 filter on the market; correct?

11 A Yes, that's correct.

12 Q So even as early as 2006, when Bard became aware of  
13 complaints of this filter migrating and this filter tilting,  
14 and perforating, Bard left the filter on the market to be  
09:36:51 15 implanted in patients. True?

16 A Yes, that's correct. These are known complications for  
17 vena cava filters.

18 Q And Bard did nothing to redesign the filter or take it off  
19 the market at that time; correct?

09:37:04 20 A We did eventually, yes, we did redesign it. We did not  
21 take it off the market, no.

22 Q As of 2006, were you aware of caudal migration and all of  
23 the other complications, Bard kept it on the market?

24 A Yes, that's correct.

09:37:18 25 Q And patients continued to receive this filter that Bard

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:37:20 1 knew had these complications that may be related to each  
2 other; correct?

3 A Yes, that's correct.

4 Q And so knowing that, Bard didn't tell doctors that its  
09:37:31 5 filter was experiencing cascades of complications, did it?

6 A I'm not sure if that statement is accurate.

7 Q Certainly you didn't, from the engineering department,  
8 tell Bard, You should notify doctors and patients that we have  
9 a filter that's caudally migrating, experiencing tilt,  
09:37:49 10 perforating, and fracturing? You didn't suggest to Bard they  
11 should be contacting doctors or they should stop selling the  
12 filter, did you?

13 A That is not my role. There are procedures to this kind of  
14 communication.

09:38:03 15 Q And you're not aware of anybody making that type of  
16 communication, are you?

17 A So I believe the clinical trial on the filter, it list all  
18 the complications, and these were also posted in the  
19 instructions for use.

09:38:23 20 Q Sir, my question is different. When Bard started as early  
21 as 2006 investigating caudal migration and started looking at  
22 the inner relationship with other complications, you're not  
23 aware of anybody from Bard that warned doctors that that was  
24 going on within Bard?

09:38:40 25 A I don't have specific recollection that this happened.

## DIRECT EXAMINATION - ANDRE CHANDUSZKO

Q And Bard, knowing that the filter was migrating, tilting, perforating, and fracturing, it was still being sold to patients and being implanted in patients; correct?

A Yes, it was still sold. Yes. That's correct.

Q And knowing that the filter was migrating downward, tilting, perforating, and fracturing, it was sold to patients well into 2007. True?

A I think the filter was on the market longer than that.

Q And that filter continued to migrate, the G2; right?

A Continued after -- I'm sorry?

Q The complaints continued to come as long as the G2 was on the market; right?

A That would be my best guess.

Q And as long as that filter was on the market, Bard continued to receive complaints while the filter was being implanted in patients --

THE COURT: Mr. O'Connor, please ask the question to the witness.

BY MR. O'CONNOR:

Q That the filter was migrating, the filter was tilting, the filter was perforating, and the filter was fracturing; correct?

A I'm very sorry. Could you repeat the question, please.

Q Sure. Bard continued to receive complaints about the failure modes as long as the G2 was on the market; correct?



DIRECT EXAMINATION - ANDRE CHANDUSZKO

09:40:18 1 A Yes, that's correct.

2 Q And even when Bard started receiving those complaints  
3 after it released the filter in 2005, it left it on the  
4 market, and Bard was well aware that it was being implanted,  
09:40:31 5 the G2 was being implanted in patients. True?

6 A Yes, that's true.

7 Q And you, sir, as an engineer, understood that a tilted  
8 filter could be harmful to a patient; correct?

9 A Yes.

09:40:53 10 Q You, sir, understood that a G2 filter that tilted and  
11 perforated through the vena cava could be harmful to a  
12 patient. True?

13 A Yes. I'm not a doctor, obviously, but, yes, these are  
14 known complications.

09:41:06 15 Q You, sir, were aware that the Bard G2 filter was  
16 experiencing all the failure modes we talked about, migration,  
17 tilting, perforation, and fracture; correct?

18 A That is correct.

19 Q And you knew that this filter was capable of doing all  
09:41:26 20 those in a single patient. True?

21 A I don't have a specific recollection whether that's the  
22 case or not.

23 Q Something that would make sense to you based upon what you  
24 know about the filter?

09:41:39 25 A It's possible, but I just don't remember any particular

CROSS-EXAMINATION - ANDRE CHANDUSZKO

09:41:42 1 case like this.

2 Q Okay. Well, certainly when patients were complaining  
3 after -- before 2007, you were aware that this filter was  
4 causing harm because of its failure modes. True?

09:41:59 5 A Yes. In some patients, yes.

6 MR. O'CONNOR: That's all I have.

7 THE COURT: Is that it, Mr. O'Connor?

8 MR. O'CONNOR: No more questions, Your Honor.

9 THE COURT: All right. Cross-examination.

09:42:22 10 MR. CONDO: Yes, Your Honor.

11 Your Honor, may I approach the clerk? I'm not sure  
12 if copies of the deposition transcripts are still available --

13 THE COURT: Yes, you can.

14 THE COURTROOM DEPUTY: They are.

09:42:59 15 MR. CONDO: They are? Then I don't need them. Okay.

16 C R O S S - E X A M I N A T I O N

17 BY MR. CONDO:

18 Q Good morning, Mr. Chanduszeko.

19 A Good morning.

09:43:12 20 Q I apologize. Apologies if I cough. I'm sucking throat  
21 lozenges and trying to recover from a cold.

22 Yesterday Mr. O'Connor started with a little bit  
23 about your background, and I'd like to tell the ladies and  
24 gentlemen -- have you tell the ladies and gentlemen of the  
09:43:32 25 jury a little bit more about your background.

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

09:43:36 1 First, where were you born, sir?

2 A I was born in Poland.

3 Q And how old were you when you came to the United States?

4 A I was 24.

09:43:47 5 Q And why did you come to the United States?

6 A I came to study in the United States of America.

7 Q Mr. O'Connor asked you a little bit about your educational  
8 background, your training and experience. Where did you get  
9 your first engineering training, sir?

09:44:05 10 A So my first engineering training, I got in Poland. I  
11 studied environmental protection for four years.

12 Q And when you came to the United States, did you study  
13 engineering?

14 A Yes, I did. I studied mechanical engineering technology  
09:44:21 15 at Northeastern University.

16 Q Did you get a degree?

17 A Yes, I did. I got a bachelor of science degree.

18 Q And when you came to the United States, could you speak  
19 English?

09:44:33 20 A Just a little bit. I learned my first 200 words before I  
21 came.

22 Q Now, do you still have or still struggle with the English  
23 language? Certain concepts? Terms? Words?

24 A Not the technical part. But other words, yes, they have  
09:44:53 25 their nuances.

CROSS-EXAMINATION - ANDRE CHANDUSZKO

Q And how do you try to manage when you answer questions, for example, in this courtroom, with nuance questions or things that you find difficult?

A Ideally --

MR. O'CONNOR: Objection. Irrelevant.

THE COURT: Overruled.

THE WITNESS: Ideally, I'll try to reduce it to more technical terms which are much more precise.

BY MR. CONDO:

Q Why did you become an engineer, sir?

A So I decided to be an engineer when I was five years old. So I'm not sure what the reason was, but math and physics always came easy to me, were my favorite subjects, and I went to school to study engineering. And also like problem-solving, so I think it was a good choice.

Q Now, most of your professional career since college has been spent with medical devices; is that correct?

A 100 percent.

Q Mr. O'Connor asked you yesterday a little bit about whether you are a licensed engineer, and you said no; correct?

A That is correct.

Q Do you need to be a licensed engineer in order to do what you do, designing medical devices and conducting tests and designing tests and doing test protocols?

A No, I don't.

CROSS-EXAMINATION - ANDRE CHANDUSZKO

09:46:29 1 Q And have you been, in your own mind at least, successful  
2 as a mechanical engineer designing IVC filters, for example?

3 A I think I am. I was.

4 Q Do you hold patents?

09:46:43 5 A Yes. I hold many patents.

6 Q Give the ladies and gentlemen of the jury an appreciation  
7 for how many patents you've been issued.

8 A Around 70.

9 Q And how many of those deal with IVC filter features?

09:47:02 10 A Probably about a quarter or a third of them.

11 Q Thank you.

12 Now, you first began working with IVC filters right  
13 out of college at NMT; correct?

14 A That is correct.

09:47:17 15 Q When did you move to Bard?

16 A In 2004.

17 Q And in what capacity did you join Bard?

18 A I was a staff engineer.

09:47:36 19 Q And when you joined the company, Bard, what were your  
20 first assignments, generally?

21 A To work on the new generation Recovery filter.

22 Q Is that what was referred to I think in testimony  
23 yesterday as the G1?

24 A G1A.

09:47:53 25 Q G1A. That ultimately became what we've been talking

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

09:47:57 1 about, the G2?

2 A That is correct.

3 Q Now, did any of the work that you did at NMT before you  
4 joined Bard, any of the kinds of tests or testing that you did  
09:48:06 5 at NMT, did that play a role in the design and development of  
6 the G2 filter when you arrived at Bard later?

7 A Yes, it did.

8 Q And can you give the ladies and gentlemen of the jury an  
9 example of the kinds of tests that were done at Bard which  
09:48:24 10 informed you and others that -- excuse me. Can you tell the  
11 ladies and gentlemen of the jury the kinds of tests that were  
12 done at NMT that informed your design decisions at Bard when  
13 you were working on the G2?

14 A So without thinking much, I -- I think all of them.

09:48:48 15 Q Okay. Let's talk about some specifics. Were bench tests  
16 done at NMT?

17 A Yes, that's correct.

18 Q And what's the purpose of bench testing?

19 A So bench testing typically try to simulate a particular  
09:49:08 20 aspect of clinical experience or patient anatomy.

21 Q And were clinical tests done at NMT on the Recovery  
22 filter, the first generation filter?

23 A Yes, they were.

24 Q In fact, I should clarify. All of the tests done at NMT  
09:49:31 25 were on the Recovery filter?

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

09:49:33 1 A Yes, that's correct.

2 Q And how about animal tests? Were animal tests done?

3 A Yes. So there were bench tests, animal tests, and  
4 clinical tests.

09:49:45 5 Q Now, were any of the bench tests that were done at NMT  
6 tests that were -- that informed your engineering decisions at  
7 Bard with respect to the design of the G2 filter? In other  
8 words, anything from Recovery, any kinds of bench tests at  
9 Recovery that helped provide information to improve the G2?

09:50:13 10 A Yes, that's correct, because automatically the filters are  
11 similar.

12 Q Now, I want to talk a little bit about the fatigue testing  
13 done on the Recovery filter at NMT. Yesterday, Mr. O'Connor  
14 asked you a lot of questions about fracture resistance, and I  
09:50:33 15 think he also asked you about whether or not FEA testing was  
16 done and whether that was the only testing done for fracture  
17 resistance. So let's break this down a little bit, if we can.

18 What is an FEA test?

19 A So FEA stands for finite element analysis. It is a  
09:50:59 20 computer simulation. It typically looks at responses, in this  
21 case, of an implantable device to external forces or  
22 deformations.

23 Q And were other tests done at NMT, specifically fatigue  
24 testing, on the Recovery filter?

09:51:24 25 A Yes, there was a test like that.

CROSS-EXAMINATION - ANDRE CHANDUSZKO

Q Would you look at, I believe it's Defense Exhibit 5233, which should be in a red manila folder. And it should have a blue cover on it. Or face sheet.

A 5233?

Q 5233. Exhibit 5233. Do you have that in front of you, sir?

A Yes, I do.

Q Can you identify that exhibit? What is the title and the date?

A It's titled EnduraTEC Corrosion and Fatigue Testing of RNF Filters Design Verification, and the date is June 28, 1999.

Q And are you the author of this exhibit?

A Yes, I am.

MR. CONDO: Your Honor, we would offer Exhibit 5233.

MR. O'CONNOR: No objection.

THE COURT: 5233 is admitted.)

(Exhibit 5233 admitted.)

MR. CONDO: May it be published?

THE COURT: Yes.

MR. CONDO: Thank you.

BY MR. CONDO:

Q We put up the first page so the ladies and gentlemen of the jury can see the title of the test.

Now, this is also called a standard operating procedure?



## CROSS-EXAMINATION - ANDRE CHANDUSZKO

09:53:02 1 A Yes.

2 Q Is this a test protocol?

3 A Yes, that's what it says.

4 Q Now, was a test run according to this test protocol that  
09:53:22 5 you authored?

6 A Yes, that's what it looks like.

7 Q All right. Well, let's turn, if we can, to the next page  
8 of Exhibit 5233.

9 MR. CONDO: And if we could highlight, please, the  
09:53:42 10 purpose, and bring it forward so it is a little clearer.

11 BY MR. CONDO:

12 Q What was the objective of this test, sir?

13 A The objective of this test was to accurately evaluate ten  
14 years equivalence of corrosion/fatigue endurance of 16 RNF,  
09:54:05 15 removable Nitinol filters, by inducing a cyclic stress state  
16 in a simulated physiological environment. The duration of the  
17 experiment will be equivalent to ten years of pulmonary  
18 output, which is 32 million cycles.

19 Q Why was NMT interested in running a ten-year equivalent  
09:54:30 20 study of the endurance of the filter?

21 A So the filter, when it's implanted in a vena cava, it  
22 undergoes cyclic compressions. This has to do with the fact  
23 that when we're breathing, that causes the cava to expand and  
24 contract. And this is a standard test for implantable device  
09:54:57 25 to test to ten years, and it's time to make sure that the

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

09:55:00 1 filter would not break due to these deformations.

2 Q And what does it mean in the objective where it is written  
3 that you are inducing a cyclic stress state in a simulated  
4 physiological environment?

09:55:22 5 A Because the testing has to be -- before the filter can be  
6 implanted, the testing needs to be done in a laboratory. So  
7 there is a special machine that also has saline to simulate  
8 blood, and the test is simulating about the deformations, and  
9 also the corrosive environment of the blood.

09:55:50 10 Q Now, let's look at the test results. Can you look at  
11 Exhibit 5234, please. It should be in that red manila folder.

12 A I have it.

13 Q Can you identify the title of that report and the date  
14 please, sir?

09:56:09 15 A The title is "EnduraTEC Corrosion/Fatigue Testing of RNF  
16 Filters Design Verification," and the date is August 4, 1999.

17 Q Is this the report that reports the results of the testing  
18 from the standard protocol we just looked at?

19 A Yes, it does.

09:56:36 20 Q And does your signature appear as approving this report?

21 A Yes.

22 MR. CONDO: Your Honor, we would offer Exhibit 5234.

23 MR. O'CONNOR: No objection.

24 MR. CONDO: May it be published?

09:56:50 25 THE COURT: I'm sorry, I couldn't hear what you said,

CROSS-EXAMINATION - ANDRE CHANDUSZKO

09:56:52 1 Mr. O'Connor.

2 MR. O'CONNOR: No objection.

3 THE COURT: 5234 is admitted, and you may publish.

4 (Exhibit 5234 admitted.)

09:57:03 5 BY MR. CONDO:

6 Q I want to move quickly, sir, and I want to turn to the  
7 next page, page 2.

8 MR. CONDO: And, Scott, if you could enlarge and  
9 bring forward the extract paragraphs -- excuse me, the  
09:57:17 10 abstract paragraphs.

11 BY MR. CONDO:

12 Q Yesterday you were asked a lot of questions, and today,  
13 about the knowledge of the inferior vena cava and how it  
14 operated. I want to talk a little bit about the findings of  
09:57:37 15 this report and what that information provided, what kind of  
16 information is provided to you in the design of the G2 filter.  
17 Even though this was done for Recovery.

18 You understand me?

19 A Yes.

09:57:51 20 Q That was a little long, so I'll try to do a better job.

21 Let's look at the first paragraph.

22 You are -- the report recites that: Pulmonary  
23 functions produce a measurable IVC diameter change of about  
24 one millimeter.

09:58:15 25 Do you see that?

CROSS-EXAMINATION - ANDRE CHANDUSZKO

09:58:22 1 A Yes, I do.

2 Q Is that measurable IVC diameter change distention?

3 A Yes, that's measurable.

4 Q And when we talk about diameter change, we're talking  
09:58:37 5 about the concept of distention; correct?

6 A Yes.

7 Q All right. So what pulmonary functions produce the  
8 measurable diameter change or distention in the IVC filter?

9 A Just breathing.

09:58:52 10 Q Inhaling, exhaling?

11 A Yes, that's correct.

12 Q Now, the extract also says that the IVC filter is a  
13 corrosive environment. Do you see that?

14 A Yes, I do.

09:59:11 15 Q Why is the IVC filter a corrosive environment?

16 A So if I'm correct, it's not IVC filter.

17 Q I'm sorry, the IVC itself, the inferior vena cava. Thank  
18 you for correcting me.

19 A Yes. The blood in the vena cava, yes.

09:59:32 20 Q So why is it corrosive?

21 A It's not very corrosive, but it's corrosive enough to be  
22 of consideration because there are different salts that are in  
23 blood, and effectively water and salt will produce a corrosive  
24 environment.

09:59:51 25 Q So what was the result of this testing?

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

09:59:58 1 A So my recollection is the result was all filters passed  
2 the test.

3 Q All right. And all 16 filters were subjected to  
4 36 million cycles?

10:00:10 5 A Yes, that's correct. Of compression and expansion.

6 Q And that was equivalent of ten years of normal breathing  
7 and cardiac function?

8 A Yes. So if I remember correctly, to be exact, I think it  
9 was the 32 million that was the equivalency, and the test was  
10:00:32 10 just upped to 36, which is a little bit more.

11 Q And as an engineer, is this a reasonable test, in your  
12 opinion, to perform in order to understand the vena cava  
13 environment?

14 A Yes. It's a reasonable test to perform to understand how  
10:00:51 15 the filter would react to breathing, yes.

16 Q And after you completed this test, did you end the test  
17 there?

18 A No. In fact, we didn't.

19 Q What did you do?

10:01:06 20 A So once we met the acceptance criteria, which was no  
21 fractures, no pits, so effectively no signs of corrosion, we  
22 decided to continue with the test to 400 million cycles, which  
23 is above and beyond what was required for this test.

24 Q And what is the equivalence in years of a 400 million  
10:01:34 25 cycle test?

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:01:37 1 A So depending on the respiratory rate, it would be  
2 roughly -- it would be at least, I'd say, 50 years or more of  
3 a human life equivalency.

4 Q What do you mean by respiratory rate?

10:01:54 5 A So just breathing.

6 Q How fast you breathe? Inhale, exhale?

7 A Yes, for the whole cycle. Breathe in, breathe out is one  
8 cycle. So that was 400 million breathing in and breathing  
9 out, effectively.

10:02:08 10 Q Now, this EnduraTEC fatigue and corrosion testing of the  
11 Recovery filter, was it repeated for the G2 filter?

12 A This particular test was not.

13 Q Why not?

14 A There's a number of different reasons I can think of. So  
10:02:29 15 one reason was that the Recovery filter and the G2 filter,  
16 they shared the same material and the same manufacturing  
17 methods, so that was one.

18 Two, the Recovery filter was already subjected to  
19 400 million cycles. We knew that there were some changes in  
10:02:52 20 the G2 filter that would affect fatigue life. And the main  
21 changes for this particular test, I'm going to say that it was  
22 the change in the filter arm geometry, and then change in the  
23 filter hook.

24 So just based on sound engineering judgments, we knew  
10:03:18 25 these changes were beneficial, but nevertheless we ran a

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

1 computer simulation, which is the FEA, to both compressed and  
2 expanded configuration in the vena cava of the same size as  
3 the fatigue test on the Recovery filter, and we found that the  
4 stresses in both the arms and the hooks were significantly  
5 reduced in G2 relative to the Recovery filter.

6 There was one more test that we did, which was an  
7 actual physical test that looked at larger, much larger,  
8 deformations than the fatigue test on the Recovery filter, so  
9 we tested both G2 and the Recovery filter side by side. And  
10 what we found, that in this test, the G2 filter had a fracture  
11 resistance that was 12 times higher than the Recovery filter  
12 in the arms.

13 Q Thank you.

14 Now, we'll get into those specific tests a little  
15 later in your testimony. I want to change subjects now, if I  
16 can.

17 We talked a lot about -- you were asked a lot about  
18 the changes yesterday in the G2 filter. I have prepared a  
19 demonstrative exhibit, and that is Exhibit Number 7875. If  
20 you would put that in front of you, sir.

21 A I have it.

22 Q Now, at my request, did you look at Exhibit 7875 to  
23 determine if the information in that exhibit is correct and  
24 fairly and accurately depicts both the Recovery filter and the  
25 G2 filter?

CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:05:43 1 A I did.

2 Q And would this demonstrative help you to explain your  
3 testimony to the jury, to explain the changes that were made  
4 and the reasons for the changes?

10:06:00 5 MR. O'CONNOR: Your Honor, this is beyond the scope  
6 of my examination of this witness.

7 THE COURT: Overruled.

8 THE WITNESS: Yes, very much so.

9 MR. CONDO: Your Honor, may we publish the  
10 demonstrative exhibit to the jury?

11 THE COURT: Any objection?

12 MR. O'CONNOR: No objection.

13 THE COURT: Yes, you may.

14 MR. CONDO: Thank you.

10:06:22 15 BY MR. CONDO:

16 Q There are several pages to this exhibit, and I want to  
17 take them individually, but I do want to move quickly,  
18 Mr. Chanduszeko.

19 Can you explain what the jury is looking at on the  
10:06:38 20 first page of Exhibit 7875, the side-by-side comparison of the  
21 Recovery and G2.

22 A Yes.

23 Q Would you do so.

24 A I'm sorry?

10:06:53 25 Q Would you please do so.



## CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:06:54 1 A Yes. So what you see is comparison of the Recovery  
2 filter, which is the actual image of the filter on the left,  
3 and then an image of the G2 filter on the right.

4 Q And there are a number of indications on the G2 image of  
10:07:16 5 changes from the Recovery filter; correct?

6 A Yes, that's correct.

7 Q On this slide -- first of all, this slide doesn't reflect  
8 all of the changes, does it?

9 A That's correct.

10:07:29 10 Q There will be a later slide that has additional changes.  
11 But what changes are shown on this slide?

12 A So it shows changes to the hook, the leg span, and the  
13 arms.

14 Q And in filter language, we have adopted, or the company  
10:07:47 15 has adopted, sort of human traits to refer to different  
16 elements of the feature?

17 A That's correct, yes. Should I explain?

18 Q Yeah, go ahead.

19 A So generally speaking, we can say there's three different  
10:08:01 20 components. One is the tip, then you have two other features.  
21 One, they're called legs. So these are the longer parts that  
22 end with hooks, and the other one is the arms. So these are a  
23 little shorter and have a bend toward the top.

24 Q So the shorter elements are the arms?

10:08:28 25 A Yes. And then if you look at the arms, right below the

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:08:31 1 tip is something we call the neck area. And then the bend we  
2 will call either a shoulder -- probably shoulder, and then the  
3 very bottom of it where there is a little bend on the G2, we  
4 call that a wrist.

10:08:56 5 Q All right. Let's walk the jury through, for all of our  
6 benefits, the terminology.

7 The tip is what part of the filter in the image?

8 A The very top of it, the sleeve.

9 Q And the neck area is immediately below the tip?

10:09:07 10 A That's correct.

11 Q Then we have the arms?

12 A Yes.

13 Q And at end of the arms we have a bend. And what is that  
14 feature called?

10:09:18 15 A So at the very end, we call it a wrist.

16 Q And then we have legs, the longer features?

17 A Yes, which end with hooks.

18 Q So on this image, what were the changes between G2 and  
19 Recovery?

10:09:37 20 A So specifically or generally?

21 Q As shown on this image.

22 A So elastic hooks making the hooks stronger is one change.  
23 Then increasing the leg span, making it wider, and then  
24 increasing the length of the arms.

10:09:54 25 Q All right.

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:09:54 1 MR. CONDO: Let's go to the next slide, please.

2 BY MR. CONDO:

3 Q Why was the leg span increased?

4 A So in response to some of the migration complaints, we  
10:10:13 5 wanted to make sure that the hooks can always be engaged even  
6 if the cava distends beyond its indicator range. So that was  
7 the main -- that was the main reason.

8 Q To improve what kind of characteristic, unfavorable  
9 characteristic?

10:10:41 10 A Migration resistance.

11 Q Were the hooks also intended to resist or affect caudal  
12 migration?

13 A Yes, that's correct.

14 Q And how do these hooks, how were they intended to affect  
10:10:56 15 caudal migration?

16 A So the legs have a wider span and more radial force than  
17 what they had on the Recovery filter. And also the hooks  
18 being stronger, they would engage more readily post  
19 implantation and would stabilize the filter in both  
10:11:17 20 directions.

21 Q Now, were the primary complaints of migration of the  
22 Recovery filter cranial migration?

23 A Yes, that's correct.

24 Q Not caudal migration?

10:11:29 25 A That's correct. So cranial is up and caudal is down. So

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:11:32 1 cranial.

2 Q So let's turn to the next page, if we can.

3 Why were the hooks thickened?

4 A So the hooks were thickened to increase the cranial

10:11:51 5 migration resistance. So increasing the thickness would make  
6 the hooks stiffer.

7 Q Is designing a filter a series of balancing different  
8 decisions and characteristics? If you want to a retrievable  
9 filter, you have to balance those which permit retrievability  
10:12:13 10 with those that perhaps influence migration resistance and  
11 centering and all the other characteristics?

12 A It always is. There is a lot of conflicting requirements  
13 for this device.

14 Q And I think you said several times to Mr. O'Connor that  
10:12:34 15 when you were designing the G2, you were considering all of  
16 the harmful characteristics of the -- that may be present in a  
17 filter.

18 A That is correct.

19 Q And you were trying to address multiple complications that  
10:12:49 20 had been reported.

21 A Yes. We always do.

22 Q And Mr. O'Connor asked you a series of questions right at  
23 the end about you knew about perforation and fracture  
24 resistance and migration resistance. Do you remember those  
10:13:04 25 questions?

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:13:05 1 A Just roughly, yes.

2 Q All right. You've known about each of those items,  
3 fracture resistance, migration resistance, tilting,  
4 perforation, for as long as you've been working in filters;  
10:13:19 5 correct?

6 A That is correct. The filters have been on the market  
7 since at least the 1970s, and they're well-established devices  
8 and these are known complications.

9 Q They're known complications to designers?

10:13:33 10 A That's correct.

11 Q Known complications to people who utilize the filters?

12 A Yes.

13 Q Now, let's turn, if we can, to the next page, the increase  
14 in the curvature of the arms.

10:13:53 15 You referred to this earlier as the neck?

16 A Yes, that's correct.

17 Q Why did you increase the curvature of the arm wires coming  
18 out of the tip?

19 A So we wanted to improve our fracture resistance of the  
10:14:09 20 Recovery filter, and we looked at different possible ways to  
21 do it, and that was one way that would distribute the loads  
22 that were put on the arm over a larger area, and therefore  
23 would lower strains and stresses in the arms and hands. It  
24 would increase the fracture resistance of the filter.

10:14:32 25 Q So the Recovery had arms and legs, but particularly arms,

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:14:38 1 that came out at a greater angle below the tip; correct?

2 A Yes. I would describe it, I think better, as a smaller  
3 radius at the neck.

4 Q All right. And by radius, what do you mean?

10:14:55 5 A So the arm comes out from the tip as a straight piece of  
6 wire, and then the way its manufactured, it is bent around  
7 a -- effectively a round part of the fixture, and then it  
8 joins another straight part. So the part where it bends, it  
9 actually follow a circle.

10:15:19 10 Q Now, was the change in the curvature of the arm wires  
11 intended to improve fracture resistance in the G2 in that  
12 area?

13 A Yes, that's correct.

14 Q But that style change was not the only change that was  
10:15:31 15 made to improve fracture resistance overall in the G2 filter;  
16 correct?

17 A Yes, that's correct.

18 Q Now, did the changes to the G2 over the Recovery require  
19 redesigning the deployment system for the G2?

10:15:47 20 A Yes, they did.

21 Q And why?

22 A So the main difficulty was after we increased the  
23 thickness of the hooks, the way the hooks were loaded on the  
24 Recovery filter, they were effectively straightened out and  
10:16:05 25 they would sit, and there was a special part of the delivery

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:16:09 1 system that held the straight hooks apart so the legs wouldn't  
2 get entangled during delivery. So these much stronger hooks,  
3 we couldn't just straighten them out the same way as we did  
4 with the Recovery filter, so we had to find a different way to  
10:16:28 5 deliver the filter.

6 MR. CONDO: Now let's go to the very last slide on  
7 this exhibit, please.

8 BY MR. CONDO:

9 Q Why was the arm length of the G2 increased, and why was  
10:16:43 10 there a curved arm end added to the -- or a wrist added, to  
11 the G2?

12 A So the Recovery filter arms, because they were relatively  
13 short, they would engage more readily in a vena cava wall.  
14 And then we had some observations that when the arm engages  
10:17:12 15 this way, sometimes it may lead to the arm catching on  
16 adjacent anatomy, such as another vessel that was connected to  
17 the vena cava. So -- and that may lead to increased stresses  
18 and potentially a fracture. So we increased the length of the  
19 arm and added the wrist to -- so the arm would be parallel to  
10:17:43 20 the wall of the vena cava and would not engage as readily.

21 Q In your opinion, were all of these changes that you've now  
22 discussed intended to make the G2 filter a better filter?

23 A Yes. Hundred percent.

24 Q Now I want to change subjects again.

10:18:04 25 MR. CONDO: You can take that off, please.

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:18:06 1 BY MR. CONDO:

2 Q And I want to talk about some of the deposition testimony  
3 that Mr. O'Connor read to you yesterday.

4 If you have your deposition of October 10, 2013, in  
10:18:19 5 front of you. That's one of those large exhibits.

6 A Yes, I have it.

7 Q Okay. Now, my notes show that he asked you a question  
8 that started on page 36, lines 10 through 14.

9 A I see it.

10:19:08 10 Q He asked you: Was one of the project goals for  
11 redesigning the filter to improve in respect to tilting?

12 And you said: Generally speaking.

13 MR. O'CONNOR: Excuse me, Your Honor, I don't think  
14 the entire question was read.

10:19:25 15 THE COURT: Please reread it, Mr. O'Connor.

16 MR. CONDO: Sure. I apologize. The danger of trying  
17 to go faster than I should.

18 BY MR. CONDO:

19 Q "Question: You didn't answer my question. Was one of the  
10:19:37 20 project goals for redesigning the Recovery filter into the G2  
21 filter to improve its performance in respect to tilting?"

22 What was your answer?

23 A "Generally speaking, no."

24 Q Now, why did you use the term "generally speaking, no"?

10:19:55 25 A So first of all, I had to rely on my recollection of



## CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:19:59 1 events, and my recollection is that there were two main goals  
2 to redesign the Recovery filter. One was to improve migration  
3 resistance, and the second one was to improve fracture  
4 resistance. And these are my recollection were the main  
10:20:21 5 goals. And, however, in the design process, we don't ignore  
6 any other characteristics, so we take into consideration  
7 everything else. That's why generally speaking, no, but  
8 knowing that we test for everything and we couldn't build a  
9 filter that would simply ignore some of the other things.

10:20:46 10 Q Now, I'd like to show the jury a different part of that  
11 same deposition testimony. These are the questions and  
12 answers that immediately precede, that are in front of what  
13 you've just read.

14 MR. CONDO: Can we go to page 35, line 16, please.

10:21:01 15 And can you put page 36 side by side.

16 Page 35, line 16, through page 36, line 9.

17 BY MR. CONDO:

18 Q All right, I'm going to ask the questions, you read the  
19 answers. Is that fair?

10:21:55 20 A Yes.

21 Q Question: Line 16, page 35. "And what were the goals of  
22 the G2 filter, the redesign of the Recovery filter into the G2  
23 filter?"

24 Ignore the objection. You may read.

10:22:10 25 A "My best recollection as far as the project goals for G2

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

1 was to -- that's my best recollection, to make a filter that's  
2 more migration resistant and more fracture resistant than the  
3 Recovery filter."

4 Q "And that was it?"

5 A "That's my best recollection."

6 Q "Question: Had nothing to do with tilting?"

7 A "Not as a main goal, is my recollection."

8 Q "Question: Did it have anything to do with tilting?"

9 A "It was always a consideration for any performance, so  
10 generally speaking, every new filter that would be developed  
11 would be a consideration for tilting."

12 Q And that's what you told Mr. O'Connor yesterday when you  
13 testified; correct?

14 A That's what I meant when I testified, yes.

15 Q Now, I want to go to another section. This is also in the  
16 October 10, 2013, deposition. This is page 275. Lines 16  
17 through 23.

18 Yesterday you were asked this question, and this was  
19 the answer that was read by Mr. O'Connor. He asked you:

20 "What would predispose the G2 filter to caudal migration over  
21 the Recovery filter?"

22 Read your answer, please.

23 A "I think the hypothesis is that since the Recovery filter  
24 arms, they engage in the cava wall, which, you know,  
25 occasionally causes the saluting arm, the G2, they don't

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

engage as readily, and, therefore, they be less resistant to the caudal migration."

Q Why did you start with "I think the hypothesis is" in your answer?

A Because we don't know that for a fact.

Q This is just one theory that was being explored?

A Yes. We looked at any possible explanation.

MR. CONDO: Now if we could turn to the June 21 deposition. Page 241.

Lines 19 through 22, please.

BY MR. CONDO:

Q I believe this was a question and answer that was read yesterday. "Question: Would you agree that electropolishing is good because it helps with fracture resistance?

"Answer: If it helps? Yes."

Q Now, I'd like to go on and show the ladies and gentlemen of the jury the balance of the questioning that immediately followed that question and answer.

MR. CONDO: Can you show the ladies and gentlemen of the jury on page 241, starting at line 23, down through page 242, line 8.

BY MR. CONDO:

Q All right. Immediately after we saw the question and answer that we just read to the ladies and gentlemen of the jury, you were asked this question -- I'll ask the questions,

## CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:26:32 1 you read the answers, please.

2 "Question: Do you know -- were you aware in 2005  
3 when the G2 was being developed that it did?"

4 Then there was an objection to form.

10:26:46 5 "That is" -- and you read the answer.

6 A "I've seen evidence that it does and I've seen evidence  
7 that it doesn't. Part of it is from my professional  
8 experience, I have seen both. It's very difficult to say up  
9 front that it would actually help."

10:27:05 10 Q So there is a question, there was a question in the design  
11 and development of the G2 as to whether electropolishing would  
12 be helpful or harmful; correct?

13 A Yes, that's correct.

14 Q And that's what you were explaining to Mr. O'Connor  
10:27:20 15 yesterday?

16 A Yes.

17 MR. CONDO: Now, I'd like to go to page 267 of the  
18 same exhibit. Excuse me, same deposition. June 21, 2013.

19 BY MR. CONDO:

10:27:33 20 Q And you were asked a question, the end of 267, line 25,  
21 continuing on to the top of page 268, line 5.

22 "Question: You were asked -- were you asked to work  
23 on a design or to develop a design for the G2 that would  
24 design out that risk?"

10:28:19 25 What was your answer?

CROSS-EXAMINATION - ANDRE CHANDUSZKO

10:28:21 1 A "I was asked to minimize any risk possible."

2 Q "Could you design out the risk?"

3 A "It is not possible to design out every risk."

4 MR. CONDO: Now, I want to show the jury what the  
10:28:36 5 next question and answer was right after this question and  
6 answer. Lines 6 and 7 from page 268, please.

7 MR. O'CONNOR: I'm sorry, what page?

8 MR. CONDO: 268, lines 6 and 7. Same page we're on.

9 MR. O'CONNOR: No, that's the next page.

10:29:09 10 MR. LOPEZ: Right here.

11 MR. O'CONNOR: Okay. Thank you.

12 BY MR. CONDO:

13 Q Question, page 268 line 6: "Did you succeed?"

14 Would you read your answer.

10:29:25 15 A "I think I did."

16 Q Thank you.

17 THE COURT: All right. Mr. Condo, we're going to  
18 break at this point.

19 Ladies and gentlemen, we'll take a 15-minute break  
10:29:35 20 and plan to resume at a quarter to the hour. Please remember  
21 not to discuss the case. We'll see you then.

22 (The jury exited the courtroom at 10:30.)

23 THE COURT: All right. We'll see you in 15 minutes.

24 (Recess taken from 10:30 to 10:46. Proceedings resumed  
10:46:39 25 in open court with the jury present.)

REDIRECT EXAMINATION - ANDRE CHANDUSZKO

10:47:55 1 THE COURT: Thank you. Please be seated.  
2 Go ahead, Mr. Condo.  
3 MR. CONDO: Your Honor, that concludes my examination  
4 at this time of Mr. Chanduszeko.  
10:48:01 5 THE COURT: All right.  
6 Redirect?  
7 MR. O'CONNOR: Yes, Your Honor.  
8 Pull exhibit 932 back up. Greg, will you just go  
9 back to the first page.  
10:48:26 10 MR. LOPEZ: Mr. O'Connor, make sure you -- you have  
11 to ask to let it be shown to the jury.  
12 MR. O'CONNOR: Your Honor, may I again publish  
13 Exhibit 932 for this question?  
14 THE COURT: I'm sorry, which --  
10:48:42 15 MR. O'CONNOR: I want to ask him questions about 932,  
16 which I believe is admitted into evidence.  
17 THE COURT: You may, and it may be displayed.  
18 MR. O'CONNOR: Thank you.  
19 R E D I R E C T E X A M I N A T I O N  
10:48:56 20 BY MR. O'CONNOR:  
21 Q Mr. Chanduszeko, this is one of the documents we talked  
22 about before. This is the filter franchise review that's  
23 dated May 6, 2008. Do you recall when we talked about that  
24 earlier on your direct?  
10:49:10 25 A Yes, I do.

REDIRECT EXAMINATION - ANDRE CHANDUSZKO

10:49:14 1 Q And you just talked to your attorney about the changes  
2 that were made to the G2 to address various risks and  
3 complications; correct?

4 A Yes, that's correct.

10:49:29 5 Q And, again, that testimony that you -- and showing your  
6 diagram, that filter was released in 2005.

7 A Roughly around that date.

8 Q But after it was released, there were still discussions --

9 MR. O'CONNOR: Greg, can you go to page 2867.

10:49:53 10 BY MR. O'CONNOR:

11 Q But even after release, Bard still had a lack of thorough  
12 understanding of dynamics of the caval anatomy which impacted  
13 test methods; right? According to this document?

14 A That is the statement that is in this document.

10:50:15 15 Q Thank you.

16 Now, sir, we talked about bench testing that you did  
17 relative to both the Recovery and G2. Do you recall that  
18 testimony?

19 A Yes, I do.

10:50:30 20 Q And your point was that testing that was done in a  
21 laboratory using filters and tubes showed you that there were  
22 no fractures, no migrations -- or few; correct?

23 A That was one of the tests, and there were no fractures for  
24 the EnduraTEC test, which is the pulmonary cycles.

10:50:55 25 Q But you do know that after both the Recovery and the G2

## REDIRECT EXAMINATION - ANDRE CHANDUSZKO

1 were released, both those filters did fracture in human  
2 beings; true?

3 A Yes, that's true.

4 Q And isn't a purpose of a bench test -- well, whatever  
5 bench testing you did, it certainly didn't transfer to the  
6 realities of the filter being in the human being because you  
7 found out that that was different, that the filter was  
8 fracturing, unlike what your bench tests showed you; correct?

9 A I'm not sure if that is an accurate statement.

10 Q Well, you did your bench test, but once it was put in  
11 humans, you found out both filters, the Recovery and the G2,  
12 were fracturing. True?

13 A Yes, that's true.

14 Q Now, Mr. Chanduszeko, before the G2 was ever released to  
15 the market, how many people participated in any type of  
16 clinical study before the G2 was released to the market?

17 A If you can clarify what you mean by any type of animal --  
18 I'm sorry, clinical study.

19 Q There was no clinical study with the G2 in humans before  
20 the G2 was released to the market. True?

21 A Before it was released, no.

22 Q You agree with that?

23 A That's my understanding.

24 Q And in your role as an engineer with Bard -- that's where  
25 you still were; correct?



## REDIRECT EXAMINATION - ANDRE CHANDUSZKO

10:52:43 1 A Yes, that's correct.

2 Q You didn't participate in providing any information to  
3 marketing so that marketing could share with the public what  
4 you were learning in your testing and what you learned about  
10:52:55 5 the complaints that you were receiving. True?

6 A You said, sir, I did not participate?

7 Q You weren't providing information that marketing could use  
8 based upon what you were hearing in terms of complaints from  
9 the public?

10:53:13 10 A So I, as an engineer, don't get the complaint data  
11 directly. There's a special department called field  
12 assurance, and all the complaints are directed to them, and  
13 then this information is shared, would be shared to the filter  
14 team.

10:53:36 15 Q Okay. But my point is you, as an engineer for Bard, did  
16 not participate in any marketing of Bard products. Fair?

17 A Generally speaking, no.

18 Q And you, in engineering, you didn't provide any warnings  
19 to doctors out there that were using the filters, did you?

10:53:57 20 A No. That would be outside of my role.

21 Q And you talked about the design process and what you were  
22 trying to do to make improvements on complications in the G2  
23 before it was released to the market; correct?

24 A No, not correct. It was complication of the Recovery  
10:54:37 25 filter.

DIRECT EXAMINATION - MURRAY ASCH

10:54:38 1 Q I know, but what you were doing is you had the Recovery  
2 filter and the G2. The purpose of the G2 was to improve what  
3 you were learning about the Recovery filter after it was out  
4 in the market and in human beings.

10:54:51 5 A Yes.

6 Q And you started that while the Recovery was on the market;  
7 correct?

8 A That is correct.

9 Q And you knew that the problems the Recovery was  
10 demonstrating in terms of the failures and complications had  
11 to be improved in the new generation filter; correct?

12 A So that was the goal of the project, to improve these  
13 things.

14 Q And with that goal, knowing when that goal started, Bard  
15 still continued to sell the Recovery; true?

16 A That is correct.

17 MR. O'CONNOR: That's all I have.

18 THE COURT: All right.

19 Thank you, sir. You can step down.

10:55:42 20 All right. Your next witness, Counsel.

21 MR. LOPEZ: Plaintiffs at this time would like to  
22 call Dr. Murray Asch.

23 THE COURTROOM DEPUTY: Sir, if you'll please come  
24 forward and raise your right hand.  
25

DIRECT EXAMINATION - MURRAY ASCH

**MURRAY ASCH,**

called as a witness herein, after having been first duly sworn  
or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. LOPEZ:

Q Good morning, Dr. Asch.

A Good morning.

Q It is Dr. Asch; correct?

A Yes, correct.

Q And you are a medical doctor?

A Yes, I am.

Q And you currently practice medicine somewhere?

A Yes.

Q And where is that?

A That's in Oshawa, Ontario, a small city just outside of  
Toronto.

Q Did you travel here from the Toronto area to testify in  
this case?

A Yes, I did.

Q What did you have to do to facilitate your being here  
today?

A This being March break, vacation is a little bit difficult  
to come by, so I had to arrange for people to cover my work in  
my absence so I could be here today.

Q And did we, being the lawyers representing the plaintiff

## DIRECT EXAMINATION - MURRAY ASCH

10:57:56 1 in this case, Ms. Booker, agree to reimburse you for those  
2 expenses?

3 A Yes, you did.

4 Q Including your travel expenses?

10:58:05 5 A Yes.

6 Q And what it cost you to get someone to cover for you?

7 A Yes.

8 Q Before we get into your background and why you're here and  
9 some of the specifics about that, would you just tell the

10:58:21 10 Judge and jury generally what your prior relationship was with  
11 NMT and Bard.

12 A So when you say prior, what -- when -- what time period  
13 are you referring to?

14 Q Talking about the time period when the Recovery filter had  
10:58:45 15 not been released to the market and you were involved in doing  
16 some testing for them.

17 A Well, so the initial relationship related to this filter  
18 started in approximately 1999, when I was approached by a team  
19 composed of people from both Bard and NMT, when they asked if  
10:59:05 20 I would be involved in using their filter as a first -- as a  
21 first human use.

22 Q And prior to that, had you used Bard products?

23 A Yes, I had used Bard products for a number of years.

24 Q And had you prior to that used a IVC filter?

10:59:26 25 A Yes, I used the permanent IVC filter manufactured or sold

DIRECT EXAMINATION - MURRAY ASCH

10:59:31 1 by Bard prior to that, yes.

2 Q And did you have a good experience with that filter?

3 A Yes, I did.

4 Q Did you experience any complications with that filter in  
10:59:41 5 your practice that caused you concern about patient safety?

6 A No complications that were unexpected.

7 Q Had you ever had a Simon Nitinol filter in the years you  
8 were using it be challenged by a clot and migrate towards the  
9 heart?

11:00:00 10 A No. I had a number of filters that were challenged by  
11 clots, but none of them migrated.

12 Q And let's learn a little bit more, get some details about  
13 you, Dr. Asch. You provided us with your curriculum vitae. I  
14 think it's current. And it's Exhibit 5332. I'll ask you to  
11:00:24 15 look at that. It should be on your screen, hopefully, and on  
16 mine.

17 A I don't see it.

18 Q It's coming.

19 4332.

11:00:42 20 MR. WOODY: Oh, 43?

21 MR. LOPEZ: Did I say it wrong?

22 THE COURT: What's the number?

23 MR. LOPEZ: I said it wrong, Your Honor. I said 53.

24 It's 4332.

11:00:55 25 THE COURT: All right.

## DIRECT EXAMINATION - MURRAY ASCH

11:00:55 1 BY MR. LOPEZ:

2 Q Dr. Asch, is that a copy of your curriculum vitae that you  
3 provided us with within the last few days?

4 A Yes. That is the most current version, yes.

11:01:04 5 Q You can probably rattle off some of this stuff without  
6 looking at it. If you need to reference it, we'll go to it.

7 You went to medical school; correct?

8 A Correct.

9 Q Where did you go to medical school?

11:01:14 10 A London, Ontario University of Western Ontario.

11 Q Did you do what we commonly call an internship and a  
12 residency after medical school?

13 A Yes.

14 Q Looks like you did internal medicine residency for a  
11:01:33 15 while, and then did a radiology residency?

16 A Yeah. At the time I graduated there was no direct path  
17 into radiology, so I did two years of internal medicine as  
18 pretraining, if you will, before I was accepted -- or I was  
19 able to be accepted into the radiology residency training  
11:01:53 20 program.

21 MR. LOPEZ: Your Honor, may I offer up 4332 into  
22 evidence at this time.

23 MR. NORTH: Objection, Your Honor. Cumulative.

24 THE COURT: Overruled.

11:02:02 25 4332 is admitted.

## DIRECT EXAMINATION - MURRAY ASCH

09:25:03 1 (Exhibit 4332 admitted.)

2 BY MR. LOPEZ:

3 Q If you look at -- why don't we go to page 2 of that  
4 exhibit. I think it's page 2. Yes. Looks like you did  
11:02:18 5 radiology residency, which I think you just talked about.

6 Tell me about -- tell us about the Armed Forces Institute of  
7 Pathology at Walter Reed Medical Center. What was that all  
8 about?

9 A So that's an educational experience that many radiologists  
11:02:34 10 from around the world attend. It's a six-week intensive  
11 course on pathology and radiology correlation. So it's a  
12 really great way to put everything together and it's a great  
13 educational experience, and I was lucky enough to be able to  
14 attend that.

11:02:49 15 Q So you did a four-year residency in radiology, and then it  
16 looks like after that, in 1989, you did a fellowship in  
17 abdominal imaging and interventional radiology?

18 A That's correct. So after my initial four years of  
19 radiology training, I felt that I wanted to get more training,  
11:03:06 20 specifically in my areas of interest, which were  
21 interventional radiology and body imaging. For example, CT,  
22 MR, and ultrasound.

23 MR. LOPEZ: I made the same mistake that I reminded  
24 Mr. O'Connor about. May we publish this to the jury,  
11:03:26 25 Your Honor?

## DIRECT EXAMINATION - MURRAY ASCH

11:03:27 1 THE COURT: You may.

2 MR. LOPEZ: Thank you.

3 BY MR. LOPEZ:

4 Q Then if you go down just past the middle of that page, I  
11:03:37 5 notice you're a member of American Board of Radiology. You're  
6 a Canadian physician but -- does that mean you're  
7 board-certified in radiology in the United States?

8 A Yes, that's correct.

9 Q Then you did a certification at Harvard Medical School.  
11:03:55 10 Everyone likes to brag about going to Harvard, so I'm going to  
11 let you do it too. In 1999. What is that all about?

12 A I thought that was an important opportunity. Crisis  
13 occurs every day in all of our lives, particularly in the  
14 interventional radiology suite where bad things can happen  
11:04:11 15 quickly, so I wanted to obtain additional training. And they,  
16 Harvard, has a great training program, hands-on training  
17 program, that runs us through crisis scenarios and gives us  
18 opportunity to practice, not on humans, but to practice so  
19 that we're prepared to deal with these kinds of bad events.

11:04:31 20 Q So is there a difference between a diagnostic radiologist  
21 and an interventional radiologist?

22 A Yes, there is. A diagnostic radiologist is someone who  
23 would read a CAT scan, read an X-ray if you go to the  
24 emergency room when you twist your ankle. A diagnostic  
11:04:48 25 radiologist would read those.



## DIRECT EXAMINATION - MURRAY ASCH

11:04:49 1 An interventional radiologist is someone who does  
2 procedures. Does biopsies, does angioplasties, does tumor  
3 ablation. There's really been a very wide breadth and  
4 continued development of specialized procedures that we use in  
11:05:10 5 a different way than a surgeon would use it.

6 We use X-rays, some form of X-ray or ultrasound or  
7 CT, to guide us placing a catheter, a tube, positioning a  
8 needle into someone in order to minimally invasively treat a  
9 patient. So instead of performing operations and opening  
11:05:29 10 someone up and draining an abscess, I can just use an  
11 ultrasound and put a small needle in and put a small tube in.

12 Q So would it be within the field of interventional  
13 radiology that the placement and retrieval, potential  
14 retrieval, of IVC filters would be included?

11:05:48 15 A Yes. One of the main -- well, the main people who place  
16 and receive IVC filters are interventional radiologists.

17 Q To be a radiologist, it doesn't mean you have experience  
18 placing or retrieving filters. Is that true?

19 A That's correct. The average diagnostic general  
11:06:10 20 radiologist does not have experience or expertise in placing  
21 these devices or retrieving these devices.

22 Q So there could be a diagnostic radiologist that would look  
23 at film that may -- where there may be a filter, but that  
24 radiologist might not necessarily have any experience in the  
11:06:30 25 placement or retrieval of devices; correct?

## DIRECT EXAMINATION - MURRAY ASCH

11:06:37 1 A That's an important point because not only do they not  
2 have experience in placing or retrieving, but they also have  
3 less understanding of some of the dynamics of what can happen  
4 with a filter or things to look for on radiographs or CT scans  
11:06:50 5 that may identify a complication before it becomes a more  
6 serious complication.

7 Q So if a medical device company like Bard who was selling  
8 IVC filters asked you, if I was going to call on professions,  
9 medical specialists, would you recommend they focus on  
11:07:09 10 interventional radiologists and maybe not spend as much time  
11 with the diagnostic radiologists?

12 A Yes, I would.

13 MR. NORTH: Objection, Your Honor. I believe this is  
14 expert opinion.

11:07:20 15 THE COURT: Overruled.

16 BY MR. LOPEZ:

17 Q Okay. I'm not going to take us through every single item  
18 on this CV, but there's categories. If you could just  
19 describe for us what they would entail. For example, we've  
11:07:34 20 already gone through your academic history.

21 We don't have to go through your employment other  
22 than to ask you, at one time were you affiliated with -- where  
23 was it -- Toronto, University of Toronto, in some way?

24 A So I initially went on staff at University of Toronto in  
11:08:01 25 July 1991, and then I left the University of Toronto to go to

## DIRECT EXAMINATION - MURRAY ASCH

1 my current hospital in May of 2003.

2 Q Okay. If we could look at, I think it's page 3, executive  
3 positions. What's the CIRA?

4 A That is the Canadian Interventional Radiology Association.

5 So that's the Canadian association that allows all of us  
6 interventionalists to work together, to learn together, to  
7 create policies and protocols, to educate each other, to  
8 educate noninterventional radiologists about procedures and  
9 devices in order to best serve our patients.

10 Q And at one time you were the president -- I assume it's a  
11 national association in Canada?

12 A Yes, correct.

13 Q Go to the next page. You've listed your medical societies  
14 there as a category, and you've had some honors and awards.

15 Then research endeavors and grants on the next page. You've  
16 served on a number of committees. True?

17 A That's correct.

18 Q It's all listed here; right?

19 A Yes.

20 Q If anybody wanted to know anything about the professional  
21 career of Dr. Murray Asch, they would look at this exhibit we  
22 just marked; correct?

23 A That's correct.

24 Q And there were some -- I thought this was misspelled, but  
25 refereed publications? Is there such a thing as refereed

## DIRECT EXAMINATION - MURRAY ASCH

11:09:34 1 publications?

2 A I think that is another term for peer-reviewed. So that  
3 demonstrates an element of -- I'm not sure which word to use.  
4 Sophistication. It means I didn't just write down an article  
11:09:48 5 and said whatever I wanted and had it published, kind of like  
6 the internet. What it meant was the articles under that  
7 category were scientifically and rigorously reviewed by other  
8 experts from around the world to ensure that what I was  
9 saying, what I was trying to publish, were honest and  
11:10:06 10 appropriate and real statements.

11 Q Okay. Here we call it -- is that the equivalent of being  
12 peer-reviewed here in the United States?

13 A Yes.

14 Q And in addition to the professional career in dealing with  
11:10:24 15 these various committees, has your career also brought you to  
16 work with medical device companies in helping to design and  
17 test new products?

18 A Yes. So I've been very lucky in my career as a result of  
19 my early clinical experience and successes and my educational  
11:10:44 20 and teaching experience at the university. I had been  
21 approached over the years by a number of device companies,  
22 device manufacturers, and been asked to work with them as  
23 consultant to help them with research and development and  
24 developing new devices and bringing new devices to market. To  
11:11:04 25 market. To get them into everyday use.

## DIRECT EXAMINATION - MURRAY ASCH

11:11:08 1 Q Could you be more -- can you describe how that  
2 relationship works. I mean, you as a physician practicing, or  
3 maybe in a university, and then a medical device company comes  
4 to you and you develop some type of relationship, partnership  
11:11:23 5 or some type of arrangement with them. Just describe that how  
6 that interaction is.

7 A I think partnership is a great word. It's the word I like  
8 to use. So as a physician, I know what my patient needs and I  
9 have an idea what kind of tools I may need to treat them, but  
11:11:42 10 I don't have the expertise to design -- to design a device.  
11 Whereas the research and development people, the engineers,  
12 the brilliant people out there who are involved in designing  
13 these devices, need some guidance in terms of what does the  
14 world need? What does the device need to do? How does it  
11:12:05 15 need to function? What is its role?

16 By working together, I would have meetings with the  
17 R&D teams of a number of companies, and we would talk about  
18 what do we need? I need this device or I need something that  
19 maybe will do that, something that will kill a tumor,  
11:12:21 20 something that will stop blood clots. Some device I can  
21 remove after it stopped the blood clots.

22 By telling them what I need, they can tell me what  
23 the restrictions/requirements are, and we would work together  
24 to take it through various stages of testing to ensure at the  
11:12:36 25 end of the day safe devices are available to our patients.

DIRECT EXAMINATION - MURRAY ASCH

11:12:40 1 Q So from what you described, it's a very close working  
2 relationship where both sides are trusting what the other side  
3 is doing and you're sharing information and make sure both  
4 sides reach a common goal?

11:12:52 5 A Absolutely.

6 Q And communication is an important part of that  
7 relationship?

8 MR. NORTH: Your Honor, I'm going to object. He's  
9 leading the witness.

11:13:03 10 THE COURT: Sustained.

11 BY MR. LOPEZ:

12 Q Is communication an important part of that relationship?

13 A Yes, it is.

14 Q And why is that?

11:13:11 15 A They need to know what I need and I need to know what  
16 their product will do, how it will function, what the  
17 limitations and concerns of their product are.

18 Q Now, in some of your prior experiences where you worked  
19 with medical device companies, and you say you've been  
11:13:25 20 involved in the medical aspects, clinical aspects of it, and  
21 the company's been involved in maybe some of the technical  
22 engineering and preclinical testing, have there been times  
23 when, because of some of the things you've done, they've done,  
24 that you didn't reach that goal?

11:13:42 25 A In my experience, we pretty much -- well, we usually reach

## DIRECT EXAMINATION - MURRAY ASCH

11:13:46 1 the goal. Sometimes there have been different iterations. I  
2 mean, say I've been working with a company and we came up with  
3 device X to stop someone from bleeding after a gunshot wound.  
4 So they design something, we test it out, it doesn't seem to  
11:14:00 5 work, then they'll go back to the drawing board and make some  
6 changes in it. We keep retesting and retrying until it serves  
7 both of our needs: It's a safe product and it's a product  
8 that does what I need it to do on my patient.

9 Q So are there situations where, for example, the company  
11:14:19 10 has done certain what we call -- oh. You know what, before I  
11 do that, would you explain to the Judge and the jury, the  
12 Judge probably knows, but would you explain to the jury what  
13 preclinical testing is.

14 A Well, preclinical testing means just that. Taking a new  
11:14:36 15 device and testing it in -- typically on the benchtop. So in  
16 jars, in a non- -- trying to think how to word this, I'm  
17 sorry. Testing on the benchtop, let's -- I'll just say that.  
18 If you need more clarification, I can. As number one, to see  
19 does the device break? Does the device do what we think it  
11:15:03 20 does? And then after it's been deemed to be safe and  
21 functional in that setting, then we take it typically to an  
22 animal model where we try and find an animal model that will  
23 simulate as close as possible like human -- the human person,  
24 and then we test it out in there because, again, we want to do  
11:15:21 25 everything -- we, as a team, want to do everything we can to

## DIRECT EXAMINATION - MURRAY ASCH

1 ensure that this device is safe and functions before we  
2 subject a person to it.

3 Q So when you do preclinical testing, whether it be on the  
4 bench or in animals, is the idea to try to design that testing  
5 so that it comes as close as possible to duplicating the human  
6 condition?

7 MR. NORTH: Objection. Leading.

8 THE COURT: Sustained.

9 BY MR. LOPEZ:

10 Q Well, when you design -- when preclinical testing is  
11 designed, what is the protocol with respect to its  
12 relationship to a human condition?

13 A We -- we try and think of devices, tubes, or anything that  
14 will as closely simulate both a part of the human body and the  
15 disease that we're trying to treat, and we take those things  
16 together in order to create something that we can try and  
17 benchtop again without subjecting an animal or human to it.

18 Q Okay. Let's go immediately now to your involvement with  
19 Bard and NMT as it relates to the Recovery filter. How did  
20 that come about?

21 A That came about one year at one of the national  
22 interventional radiology meetings. I was approached by a  
23 group of people, I don't remember exactly who it was, but some  
24 combination of some Bard people that I knew and had worked  
25 with previously and the people from NMT, and they said, We



## DIRECT EXAMINATION - MURRAY ASCH

11:17:10 1 have an interesting proposition, and they briefly explained  
2 that they had been working on, on the benchtop and in animals,  
3 a newly designed filter or modification of a previously  
4 existing filter that would be, could be, of great benefit to  
11:17:27 5 my patients, and they asked if I would like to be involved in  
6 the initial human testing of that device.

7 Q Okay. And what was your next step in that process? Did  
8 you approach them to find out what their preclinical results  
9 were? Did you visit any of those facilities before you  
11:17:46 10 decided it would be appropriate to do a study?

11 A Yes. So after a little discussion, the next thing was for  
12 me to visit the NMT facility, where I was given a presentation  
13 by the engineers and the team who had been working on this,  
14 and I was shown the benchtop data and the animal data that  
11:18:09 15 they had, as well as given some background into the device and  
16 where they had started and where they were now and what the  
17 planned next steps would be.

18 Q What did they tell you about the results of their benchtop  
19 and animal studies?

11:18:25 20 A They told me that the device performed as expected, so as  
21 everyone knows we're talking about the IVC filter here, the  
22 main role of the IVC filter is to protect someone from blood  
23 clots. What they had done is modified a previous device to  
24 allow that device to be removed, and so they had told me that  
11:18:44 25 in their animal experience, they were successful in safely

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11:18:49 1 removing this IVC filter.

2 Q Did they share with you any concerns they had about the  
3 thresholds they had set for any of their testing?

4 A No, they did not. They did not express any concerns at  
11:19:02 5 all.

6 Q Did they express anything to you about their not testing  
7 in animals or on the bench to worst case scenarios?

8 A They didn't give me quite all of those details. They  
9 basically said this is how we tested it and these were our

11:19:19 10 results, and they were satisfied -- they expressed they were  
11 satisfied with the results and they felt it was appropriate to  
12 proceed to the human model.

13 Q And you accepted that representation when you agreed to do  
14 whatever study it was that you did in Canada?

11:19:35 15 A Yes. Again, honesty and communication is -- are  
16 paramount. I don't have the biomechanical background to check  
17 up on the data and information they gave me. I trusted them  
18 as I had trusted other corporations that I had worked with  
19 when we were developing different types of devices.

11:19:56 20 Q Now, did they -- did someone -- strike that.

21 The facility you went to was NMT, Nitinol Medical  
22 Technologies; is that correct?

23 A That's correct.

24 Q And what was your understanding of the relationship  
11:20:11 25 between NMT and Bard?

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11:20:14 1 A It's my understanding NMT had manufactured this device,  
2 and other devices sold by Bard and other companies, and they  
3 were positioning themselves for a partnership to either  
4 ultimately go into business with respect to this device or  
11:20:26 5 potentially, down the road in the future, have Bard acquire  
6 the device. I saw it as a partnership.

7 Q What is the next step now? Let me ask you this question  
8 first: Did anyone say to you why they were going to Canada to  
9 do this study?

11:20:44 10 A Yes. They did admit that, and this is relatively common  
11 knowledge, at different times the pathway to approval for a  
12 device or the pathway to trialing a new device is easier in  
13 Canada. And they came to Canada -- they came to me, they came  
14 to Canada knowing that this would be an easier to get through  
11:21:05 15 the ethics committees and the licensing committees.

16 Q And then what did you do to help -- I mean to help further  
17 this process to get it approved so you could do this study in  
18 Canada?

19 A So working with them and the documents that they provided  
11:21:22 20 me, I went to our hospital vice president, our hospital ethics  
21 committee, and the Health Canada board to get approval, both  
22 from the health -- from both places in order to have this  
23 filter released to me and in order to be able to have  
24 permission to place this filter into patients.

11:21:47 25 Q Did you also have to contact what's known as Health

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1 Protection Branch in Canada?

2 A Yes. So that's -- yes. Those are the people I was  
3 referring to, Health Protection Branch. Yes.

4 Q Exhibit 4330, please.

5 Do you have that in front of you, Dr. Asch?

6 A Yes, I do.

7 Q Is that the letter you wrote to Health Protection Branch  
8 to seek their permission to do this study?

9 A Yes.

10 Q And this was going -- was this study the first time any  
11 human being was going to be implanted with a Bard retrievable  
12 filter?

13 A Yes, that's correct.

14 Q And this is to Dr. William Freeland. Do you see that?

15 A Yes.

16 MR. LOPEZ: May I offer this into evidence,  
17 Your Honor? Let me say I would offer this into evidence.

18 MR. NORTH: No objection, Your Honor.

19 THE COURT: 4330 is admitted.

20 (Exhibit 4330 admitted.)

21 MR. LOPEZ: May we publish this to the jury, please?

22 THE COURT: Yes.

23 BY MR. LOPEZ:

24 Q If you look at the top part of that that's being shown, it  
25 states: Request for compassionate release of

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1 temporary/retrievable inferior vena cava manufactured by  
2 Nitinol Technologies Medical, Inc., in Boston, distributed by  
3 Bard Canada.

4 Do you see that?

11:23:14 5 A Yes, I do.

6 Q And what's a compassionate release?

7 A So compassionate release allows Health Protection Branch  
8 to allow me to use a device that is not otherwise approved,  
9 either at all or approved for a specific function.

11:23:29 10 MR. LOPEZ: Could we go down to the next paragraph,  
11 Mr. Woody.

12 BY MR. LOPEZ:

13 Q And is this document to Health Protection Branch some of  
14 your activities prior to making this request?

11:23:45 15 A Yes.

16 Q For example, you visited NMT's facility, which you just  
17 talked about; correct?

18 A Yes.

19 MR. LOPEZ: Could we highlight that, please.

11:23:55 20 BY MR. LOPEZ

21 Q And you had a personal opportunity of inserting and  
22 removing these devices in their sheep model.

23 Do you see that?

24 A Yes, that's correct.

11:24:03 25 Q You got to practice on sheep before you put it in humans;

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1 correct?

2 A Yes.

3 Q And you've seen -- and you talk about seeing the testing  
4 facilities.

5 MR. NORTH: Objection. Leading.

6 MR. LOPEZ: Well, it's right in the document.

7 THE COURT: Overruled. The document's in evidence.

8 BY MR. LOPEZ:

9 Q And you reviewed the data at NMT, as the document says;  
10 correct?

11 A I was presented the data. I didn't scientifically  
12 reanalyze it or assess it for its validity. But I was given  
13 the data, yes.

14 Q Then the next sentence, you're telling Health Protection  
15 Branch that you were satisfied with what you saw at NMT, that  
16 the device was safe and efficacious. True?

17 A Yes.

18 Q And that it represents a significant improvement in  
19 technology.

20 A Yes.

21 Q And then let's go down to where it says -- where it reads:  
22 Currently NMT is planning similar testing.

23 Do you see where I am?

24 A Yes.

25 Q Following 12 weeks of filter insertion.

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11:25:12 1 See where I am?

2 A Yes.

3 Q So was your study -- why don't you tell the jury, what was  
4 the purpose of your study? What were you trying to find out  
11:25:25 5 by putting this device in human beings for the first time?

6 A The purpose of this study was to see if this filter could  
7 be removed after a prolonged period of being in place.

8 Prior to this, although there had been a number of  
9 removable filters released on the market, the -- there was a  
11:25:47 10 significant limitation, which created clinical issues and  
11 restrictions, and that limitation was approximately ten to 12  
12 days. And so the advantage of this is, by this device, was to  
13 provide a much longer window in order to increase the number  
14 of patients who could benefit from this.

11:26:05 15 And so we were simply looking at this filter. This  
16 study was meant to look the at the filter. Can we take the  
17 filter out? That's really the single question that was asked  
18 by this -- that was meant to be asked by this study.

19 Q If you drop down to the bottom of that paragraph which  
11:26:25 20 begins "This filter has been found to withstand" -- do you see  
21 where I am? -- "50 millimeters of mercury pressure" --

22 A Yes.

23 Q -- "exerted across the filter in fully occluded  
24 15-millimeter and 28-millimeter diameter vessels without  
11:26:46 25 evidence of migration."

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11:26:46 1 Did I read that correctly?

2 A Yes.

3 Q Did Bard -- was this something that you established as the  
4 appropriate pressures for testing and appropriate size, or was  
11:26:53 5 this something that had been done by either NMT or Bard?

6 A This was something done by, presumably, NMT, with the  
7 assistance of Bard, and this is information, as I say, that  
8 was presented to me. I was not involved in any of their  
9 benchtop or animal studies.

11:27:09 10 Q Did Bard ever share with you any internal -- or NMT ever  
11 share with you any internal documentation they had that that  
12 was actually too low of a threshold to test this device on the  
13 bench?

14 A No. No information like that was shared with me.

11:27:29 15 Q They didn't tell you that they had done some research in  
16 the literature and done some of their own sheep testing that  
17 suggested that the testing for migration resistance should  
18 have been more like 70 to 80 millimeters of mercury?

19 A No, that was not discussed.

11:27:50 20 Q Okay. Then the very bottom. "My use of" -- it says  
21 "produce." I assume you meant "product." I hate to point out  
22 your typographical error, but I think you meant "product";  
23 correct?

24 A Yes.

11:28:07 25 Q "Will likely constitute the first human use worldwide."



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11:28:11 1 Correct?

2 A That's correct.

3 Q Now, before we move on, there's another exhibit I want to

4 show you.

11:28:29 5 MR. LOPEZ: 2090. I'm hoping it's in here.

6 I need 2090.

7 THE COURT: I've got a copy if you want it.

8 MR. LOPEZ: You got one, I didn't.

9 THE COURT: Yeah.

11:29:22 10 MR. LOPEZ: Thank you, Judge.

11 I might have it, actually.

12 I do. I take it back. The tab was hiding.

13 BY MR. LOPEZ:

14 Q 2090. And do you recognize this document, Dr. Asch?

11:29:42 15 A Yes, I do.

16 Q And is it -- just describe what it is.

17 A So this is a slide show, general overview, introduction to

18 the filter in terms of the background of the filter,

19 background of NMT Medical, and some information about the

11:30:02 20 testing that they had done. And this was the slide show that

21 was shown to me at the time of my first visit to NMT when we

22 were reviewing, again, the background, the safety, the value,

23 the plan for this new filter.

24 Q Okay.

11:30:19 25 MR. LOPEZ: I offer at this time, Your Honor, into

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11:30:22 1 evidence.

2 MR. NORTH: No objection, Your Honor.

3 MR. LOPEZ: I'd like to publish it to the jury.

4 THE COURT: 2090 is admitted, and you may publish.

09:25:03 5 (Exhibit 2090 admitted.)

6 MR. LOPEZ: Thank you.

7 MR. LOPEZ: Let's go to page 7.

8 Let's go to Page 6 first of this document.

9 Actually, let's go to page 7. We've seen that  
11:30:46 10 picture before. Let's go to page 7.

11 BY MR. LOPEZ:

12 Q This is on the 14th of June, 2000. Do you see that?

13 A Yes.

14 Q And this describes the Recovery filter as an optional  
11:31:02 15 filter. What does that mean, optional filter?

16 A The term "optional filter" had been developed around the  
17 time that this and some other filters came out. So initially  
18 when IVC filters were developed, they were called permanent  
19 filters. People realized that there was a value in having the  
11:31:23 20 filters removed and not staying there permanently. So the  
21 next generation, if you will, was something called a removable  
22 filter, which had to be removed because it was tethered and  
23 essentially the filter was inside the person, there was a bit  
24 of it extending outside the patient, so that filter needed to  
11:31:42 25 be removed.

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1 This generation of filters, where the filter is  
2 placed and then can be removed, is called an optional filter  
3 because when it can be removed, the aim is to remove it, but  
4 if, for a variety of reasons, the filter can't be removed,  
5 there is the option of leaving the filter in place.

6 Q Now, when this presentation was given to you, were there  
7 individuals there from both NMT and Bard?

8 A Yes, there were.

9 Q And this was done at the NMT facility?

10 A That's correct.

11 Q Do you remember the names of any of the people that were  
12 there?

13 A I remember a few names. Rob Carr. Tom Kinst. Monica  
14 Coutanche. Morris Simon was there.

15 I don't remember any other names at this point.

16 Q Did Tom Kinst ever share with you the literature search he  
17 had done about the pressures within the vena cava that he  
18 found in doing a research -- in doing research to determine  
19 what an appropriate threshold, minimum threshold, should have  
20 been in testing an IVC filter in -- on the bench?

21 A Not that I recall.

22 Q So the Recovery filter, if you look at the second -- the  
23 third bullet point, the purpose was it would be the ideal vena  
24 cava filter; correct?

25 A Yes.

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11:33:11 1 Q And it should have the same strengths as permanent  
2 filters?

3 A Absolutely. That's essential.

4 Q I mean, they didn't have to write that down for you to  
11:33:23 5 agree with that. True?

6 A Correct.

7 Q Accurate placement, enhanced centering, small sheath;  
8 correct?

9 A Yes.

11:33:29 10 Q Why is centering so important?

11 A From early on in the design and use of filters, it was  
12 recognized that if a filter is not centered, if it's tilted  
13 like the Tower of Pisa, the filter can be unstable, the filter  
14 may not function in terms of protecting and stopping blood  
11:33:48 15 clots, the filter may be more difficult to be removed, and the  
16 filter is also going to be subjected to different  
17 biomechanical forces which then could increase the risk of the  
18 filter fracturing.

19 Q Okay. And was the design and goal of this filter, as far  
11:34:05 20 as you understood it, to be removable at 12 weeks?

21 A The testing they had done up to this point, they had  
22 chosen a 12-week time. So the number 12 weeks came up because  
23 they just picked a number out of a hat, they tested it in  
24 sheep up to 12 weeks with the assumption that 12 weeks is a  
11:34:26 25 great advance over the current retrievable optional filters,

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11:34:31 1 which are approximately ten days.

2 Q And was the idea that it would be retrievable within 12  
3 weeks, but if it was not retrieved within 12 weeks, it would  
4 then convert to a permanent device?

11:34:45 5 A Yes. Again, the number 12 weeks was there so, although we  
6 put 12 weeks there, or 12 weeks was put there, there was still  
7 an aim to potentially, whenever we could, remove the filter,  
8 even if it was beyond the 12-week window. But if for clinical  
9 or technical reasons the filter couldn't be removed, the  
11:35:06 10 intention of this filter was to be left in as a permanent  
11 filter.

12 Q Was your pilot study designed to test its safety and  
13 effectiveness as a permanent filter?

14 A No. The study was only designed to assess removability.

11:35:21 15 Q And if you go to the next -- to page 9, there's another  
16 PowerPoint. Actually, if you look at Page 8. Sometimes you  
17 should look at the PowerPoint before the PowerPoint. This is  
18 a cover PowerPoint that says "Recovery Filter System Design  
19 Attributes." True?

11:35:43 20 A Yes.

21 Q I apologize for the lines. When you OCR documents so you  
22 can highlight them, it does that.

23 MR. LOPEZ: Can we go to the next page, please, 9.

24 BY MR. LOPEZ:

11:35:52 25 Q Arms. Designed for centering. There's that word again.

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11:35:55 1 The arms are, what, the upper portion of the device?

2 A Yes, correct.

3 Q And according to this document, they were designed to help  
4 the centering of the filter; correct?

11:36:04 5 A Yes.

6 Q And then it says "and caudal migration resistance."

7 The arms; right?

8 A Yes.

9 Q And what is caudal migration? Not that the jury doesn't  
11:36:15 10 know that already, but --

11 A So "caudal" is a fancy word meaning down south, towards  
12 the feet. And because of the design of the arms, you can see  
13 they're really almost needle like. And so they would  
14 potentially get embedded in the caval wall to stop the filter  
11:36:32 15 from moving down towards the feet.

16 Q So you want the filter -- is the idea that once you put  
17 the filter in, you want it to stay where you put it?

18 A Yes. That's an important feature of a filter. You want  
19 it to stay where you put it because as soon as it starts  
11:36:45 20 moving around, it will function differently. Less

21 effectively. It may fail. And it may, by moving somewhere  
22 else, could cause different complications.

23 Q So you don't want to compromise moving in one direction to  
24 compromise moving in the other direction?

11:37:04 25 A That's correct.

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11:37:06 1 Q Stay where you put it.

2 A Exactly.

3 Q If you're going to represent you've taken stability to a  
4 new level, you better make sure you've taken stability to a  
11:37:14 5 new level. True?

6 A Yes.

7 MR. NORTH: Objection. Leading.

8 THE COURT: Overruled.

9 BY MR. LOPEZ:

11:37:23 10 Q And: One size fits all, up to 28-millimeters.

11 Do you see that, Doctor?

12 A Yes.

13 Q That means what?

14 A That is standard IVC filter jargon. Someone years ago  
11:37:34 15 decided that the average IVC, average vena cava, was less than  
16 28-millimeters in corrected transverse dimension, and so  
17 really all the filters were designed to be -- to fit in a cava  
18 that size and be stable in a cava that size.

19 Q Let's talk about that for one moment. When it says one  
11:37:53 20 size fits all, that means when you place it, at the time  
21 you're placing it, it should be at 28-millimeters or less;  
22 correct?

23 A Yes.

24 Q And that doesn't take into consideration the stent's  
11:38:09 25 ability, or the contraption that makes the IVC, the vena cava,

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11:38:15 1 larger; true?

2 A That's correct. That's also a very important point  
3 because the IVC is a living structure and it varies. It  
4 depends upon the hydration state of the patient, it depends on  
11:38:28 5 the pressure gradients in the body. Are they walking around?  
6 Are they lifting something? Are they lying? Are they  
7 sitting? Are they standing? So the size of the IVC can vary  
8 quite a bit depending upon patient factors and what they're  
9 doing.

11:38:44 10 Q So if I were to, like, bend over and pick up a heavy box,  
11 would that have an effect on my -- might have an effect on my  
12 vena cava if it was really, really heavy?

13 A Yes. That would make your vena cava much larger than it  
14 would if you were lying flat in bed.

11:39:00 15 Q So the idea is if you were going to recommend or design  
16 this thing to be in a 28-millimeter vena cava, you have to  
17 take into consideration that people who have these could pick  
18 things up or do things that might make the vena cava go beyond  
19 28-millimeters?

11:39:15 20 A Yes.

21 MR. NORTH: Objection. Leading.

22 THE COURT: Sustained.

23 MR. LOPEZ: Okay. Let's look at page 20 of Exhibit  
24 2090.

25



## DIRECT EXAMINATION - MURRAY ASCH

11:39:45 1 BY MR. LOPEZ:

2 Q What is an in-vivo study?

3 A In-vivo means in life. In a living organism, whether it  
4 be an animal or human.

11:40:02 5 Q Does this describe an animal study Bard had done, or NMT  
6 had done?

7 A Yes. I believe this refers to the initial sheep animal  
8 work that was done.

9 Q And does this refresh your recollection -- you can look at  
11:40:15 10 the next slide too, number 21, if you need it -- as to the  
11 type of animal study that was done prior to you doing your  
12 pilot study in humans?

13 A Yes. Those are images of the sheep cava with -- you can  
14 see the markings there. Filter arms, filter feet are labeled  
11:40:41 15 and indicated.

16 So this was after six weeks. So they wanted to look  
17 at the cava with the filter in position to see were there  
18 issues? Was there damage to the cava as a result of this  
19 filter being in place?

11:40:57 20 Q So was this animal study designed to test whether or not  
21 the filter, if it got challenged by a clot, would migrate up  
22 toward the heart?

23 A No. This animal study was simply designed to look at the  
24 filter in position and to look at the cava, if there was  
11:41:13 25 damage after the filter was removed. There was no -- there's

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11:41:18 1 no part of that study did they look at migration. They didn't  
2 test it to see if the filter stopped blood clots. There were  
3 no blood clots that were administered to the sheep. It was  
4 simply does this filter -- can the filter be removed and what  
11:41:33 5 does the cava look like.

6 Q Are you aware of any animal studies they did to determine  
7 the long-term performance of the Recovery filter?

8 A I'm not aware of any.

9 Q According to this exhibit, it looks like, if you look at  
11:41:51 10 page 20, the longest was eight weeks, I think it was, in the  
11 sheep before they were sacrificed.

12 Do you see that there?

13 A Yes.

14 Q Do you know if they ever did any animal studies to  
11:42:12 15 determine the long-term effects on a Recovery filter in any  
16 animal model to determine whether it would stay centered in  
17 the cava over extended periods of time?

18 A No. I don't believe a study like that was ever done.

19 Q Did they ever do any study to determine the dynamics of  
11:42:32 20 just an animal's everyday living might have on whether the  
21 device could fracture over time?

22 A No, they didn't look at that either.

23 Q How about whether or not it would tilt or probably migrate  
24 and potentially perforate into other organs? Was there ever  
11:42:51 25 an animal test like that with the Recovery filter, as far as

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11:42:55 1 you know?

2 A Not as far as I know.

3 Q So the first animal that the Recovery filter was implanted  
4 in to see whether or not it would behave and be safe was your  
11:43:11 5 pilot study with humans. True?

6 A Yes.

7 Q So let's go to Exhibit -- I think we talked about 4330,  
8 and that was July 21, 1999. Your letter to Health Protection  
9 Branch in Ottawa. Let's look at -- I think it's 552.

11:44:06 10 THE COURT: What's the number?

11 MR. LOPEZ: 552, Your Honor.

12 BY MR. LOPEZ:

13 Q Do you see that, Dr. Asch?

14 A Yes, I do.

11:44:21 15 Q Do you recall seeing this document when your deposition  
16 was taken in May of 2016?

17 A Yes.

18 Q And does this -- are you familiar with this letter?

19 A Yes.

11:44:39 20 Q And does this letter describe some of the questions you  
21 had prior to performing this study in Canada?

22 A Yes, it does.

23 Q And do you know who Monica -- I can't pronounce it. It's  
24 a French name. You could probably pronounce it; right?

11:44:50 25 A Coutanche.

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11:44:52 1 Q Coutanche. Do you know who she is?

2 A At that time she was the marketing manager for my  
3 division, and she was the person that I most closely worked  
4 with, with respect to this device.

11:45:06 5 Q This is a letter from Tom Kinst. I think you mentioned  
6 him earlier?

7 A Yes.

8 Q And he's identified as the product manager of vena cava  
9 filters at NMT Medical; correct?

11:45:17 10 A Yes.

11 MR. LOPEZ: I'd like to offer this exhibit into  
12 evidence at this time, Your Honor.

13 MR. NORTH: No objection, Your Honor.

14 THE COURT: 552 is admitted.

09:25:03 15 (Exhibit 552 admitted.)

16 MR. LOPEZ: Could I publish it to the jury, please?

17 THE COURT: Yes.

18 BY MR. LOPEZ:

19 Q So this is a letter from Tom Kinst, you'll see it on the  
11:45:37 20 second page.

21 MR. LOPEZ: If you can show Dr. Asch that, and the  
22 jury.

23 Let's go back to the first page, please.

24 BY MR. LOPEZ:

11:45:54 25 Q And this was regarding some questions that you had; right?

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11:45:59 1 A Yes.

2 Q And the first question was: What are the U.S. physicians  
3 who will be implanting on compassionate ground doing about, A,  
4 patient consent, B, IRB approval and, C, hospital ethics  
11:46:18 5 approval?

6 Did I read that correctly, Doctor?

7 A Yes.

8 Q I think we all know what patient consent is. What is IRB  
9 approval?

11:46:28 10 A Internal review board. So these are just different words,  
11 different corporations, different hospitals have, actually,  
12 ethics. So ethics and IRB in my world are synonymous.

13 Q And hospital ethics approval, is that basically -- I think  
14 you just said that's synonymous.

11:46:47 15 A Yes.

16 Q Okay. And Tom wrote: It turns out that the regulatory  
17 burden for using the filter on compassionate grounds are too  
18 great at this time. Our U.S. physicians will not be using the  
19 device on compassionate grounds in the U.S. in the immediate  
11:47:04 20 or foreseeable future.

21 Did I read that correctly?

22 A Yes.

23 Q Then it mentions Dr. John Kaufman and Dr. Tony Venbrux.  
24 Are you familiar with those two doctors?

11:47:16 25 A Yes, I am.

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11:47:19 1 Q And this is where it mentions: We are all interested in  
2 performing the first human implantations with Dr. Asch in  
3 Canada.

4 Correct?

11:47:28 5 A Yes.

6 Q And it says: The regulatory burden for using the device  
7 under compassionate use is greater in the U.S. and performing  
8 the first implants with Dr. Asch in Canada can provide us all  
9 with benefits: A reduced regulatory burden, earlier implants,  
11:47:46 10 and Dr. Asch's involvement with the first implants.

11 Did I read that correctly?

12 A Yes, you did.

13 Q If you go to the next page, the question reads: How many  
14 patients do you want Dr. Asch to do?

11:48:06 15 And then the next question: What types of patients?

16 And then the next question: Are there any exclusion  
17 criteria?

18 Do you see that, Dr. Asch?

19 A Yes.

11:48:18 20 Q The jury has this and it's been admitted, but I'm going to  
21 go down to the very last sentence of the first paragraph: It  
22 is the removal of the device that we would like to get  
23 clinical experience. True?

24 A Yes.

11:48:33 25 Q And that's what your understanding was of this study?

DIRECT EXAMINATION - MURRAY ASCH

11:48:36 1 A Correct.

2 Q Number 3. How long should -- I'll wait until Greg gets  
3 there.

4 Number 3. How long should the devices remain in  
11:48:46 5 patients? Does it have to be removed or can it be left in  
6 permanently?

7 You see the answer there from Tom Kinst: The devices  
8 can remain in patients up to six weeks.

9 Did I read that correctly?

11:49:01 10 A Yes, you did.

11 Q Then it says: The device does not have to be removed; it  
12 can be left in permanently.

13 That's what Tom wrote; correct?

14 A Yes.

11:49:11 15 Q And that was based on the animal and bench test data that  
16 they had at the time?

17 A Yes.

18 Q And then what test -- number 4: What tests should be done  
19 while the RVF -- does that stand for Recovery vena filter?

11:49:30 20 A Yes, it does.

21 Q Then a VQ scans for efficacy. What does VQ scans mean?

22 A Ventilation/perfusion study. It's a nuclear medicine test  
23 that's commonly used to assess patients for pulmonary emboli.

24 It's one of the standard things that could replace a CT scan

11:49:47 25 if --

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11:49:48 1 Q Then let's just go to the answer part of this.

2 A follow-up abdominal radiograph should be taken to  
3 check for filter positioning, centering, and migration.

4 Did I read that correctly?

11:50:00 5 A Yes.

6 Q Explain what that means to the jury, please.

7 A Again, since this was a new device, after we placed the  
8 device, the plan is to obtain routine follow-ups. This is a  
9 study, so normally in current standard practice, somebody gets  
11:50:22 10 sick, they need an IVC filter, the doctor puts an IVC filter  
11 in, and that's it. The patient doesn't get any regular  
12 checkups, if you will, to look at that filter.

13 But because this is a new filter that had never been  
14 used before, we thought it was important to follow these  
11:50:37 15 patients up in a way that normal patients wouldn't be followed  
16 up. So these patients were subjected to additional scrutiny  
17 so we could identify any potential complication before it  
18 became too severe.

19 Q It was an experimental device at the time that you needed  
11:50:53 20 to watch closely. Is that why?

21 A That's correct.

22 Q And, 5 says: Abdominal radiograph should be taken to  
23 assess the presence of thrombus within the filter prior to  
24 removing it.

11:51:06 25 Did I read that correctly?



## DIRECT EXAMINATION - MURRAY ASCH

11:51:09 1 A Yes.

2 Q So that's how you can find out whether or not there might  
3 be a clot in the filter?

4 A That's what it says. That's actually not an entirely true  
11:51:19 5 statement. You need to do a CAT scan or inject X-ray dye, or  
6 do a venogram that was referred to in another document, I  
7 believe, to assess for thrombus.

8 Q Okay. Thank you, Doctor.

9 You set a protocol, I take it, for this study once  
11:51:40 10 you got an IRB and the hospital ethics board agreed and the  
11 health organization in Canada, the equivalent of the FDA in  
12 Canada, said you could do this test; right?

13 A Yes.

14 MR. LOPEZ: 556, please.

11:52:24 15 If you look at Bates number 586, Greg, if you could  
16 show that to Dr. Asch.

17 BY MR. LOPEZ:

18 Q And ask if that is a summary or an outline of the study  
19 protocol?

11:52:42 20 A Yes. That is the study protocol that was submitted to  
21 Health Canada and to the hospital research ethics board in  
22 order to give them the information that would allow them to  
23 allow me to place the filter.

24 MR. LOPEZ: I'd like to offer this exhibit, 556, into  
11:53:00 25 evidence at this time, Your Honor.

DIRECT EXAMINATION - MURRAY ASCH

11:53:01 1 MR. NORTH: No objection, Your Honor.

2 THE COURT: Admitted.

3 (Exhibit 556 admitted.)

4 BY MR. LOPEZ:

11:53:06 5 Q Okay. Let's just go to this. So this is -- it sets forth  
6 the goals of this study.

7 THE COURT: Do you want this displayed?

8 MR. LOPEZ: Oh, yes, I do, Your Honor. Thank you.

9 Please publish it to the jury.

11:53:17 10 THE COURT: All right.

11 BY MR. LOPEZ:

12 Q And then it gives the background.

13 MR. LOPEZ: Greg, can you show that first paragraph,  
14 please.

11:53:28 15 MR. WOODY: Background or Goals?

16 MR. LOPEZ: The first paragraph under Background.

17 BY MR. LOPEZ:

18 Q And who wrote the protocol, Dr. Asch?

19 A Some combination of the team from NMT and Bard. I believe  
11:53:43 20 it was predominantly the NMT people, but, again, the lines

21 were blurred and I wasn't certain exactly what roles

22 individuals had. I looked at them as a unit working together.

23 Q And if you look at the second paragraph: There have been  
24 a variety of designs. However, the perfect filter is yet to  
11:54:02 25 be found.

## DIRECT EXAMINATION - MURRAY ASCH

11:54:04 1 A Correct.

2 Q Do you see that?

3 That is probably true today?

4 A Yeah.

11:54:08 5 Q Long-term complications such as filter strut fracture or  
6 perforation cause hesitancy to use these devices in children  
7 and young adults as there are no true long-term studies  
8 available.

9 Right?

11:54:23 10 A That's correct.

11 Q And then: More recently there have been attempts to  
12 design a filter that can be removed or retrieved after the  
13 period of risk of pulmonary embolism is over. In this way,  
14 the potential risk of long-term complication --

11:54:51 15 THE COURT REPORTER: Excuse me, Counsel. You're  
16 reading too fast.

17 MR. LOPEZ: I'm sorry. I'm going to withdraw that  
18 anyway and go to the next paragraph just for time purposes.

19 Greg, the second paragraph in that section.

11:54:59 20 BY MR. LOPEZ:

21 Q The new filter design -- and that would be the Recovery  
22 filter. True?

23 A Yes.

24 Q -- represents a significant benefit to patients in that it  
11:55:08 25 may be removed anytime up to four weeks following insertion.

## DIRECT EXAMINATION - MURRAY ASCH

1 In parentheses, 12 week removal data will be available  
2 shortly, end paren.

3 Did I read that correctly?

4 A Yes, you did.

5 Q And your study was going to provide the 12-week removal  
6 data; is that right?

7 A Yes. No. So the 12-week removal data was the sheep that  
8 were still waiting. So there was a second group of sheep that  
9 had 12 -- that they were going to remove the filters and  
10 examine after 12 weeks. So we were waiting -- we had gotten  
11 this submission prepared and in place with the plan to, once  
12 the 12-week data from NMT was available, to change our window  
13 to 12 weeks.

14 Q And then if you go to the second page of this document,  
15 Exhibit 556 --

16 MR. WOODY: Second page or --

17 MR. LOPEZ: I'm sorry. Next page. Thank you.

18 BY MR. LOPEZ:

19 Q Informed consent. Could you explain to the jury what is  
20 informed consent when it comes to doing a study like this.

21 A Well, anytime we do any procedure on a patient, you've all  
22 had operations or things, I'm sure, the doctor, the person  
23 performing the procedure, needs to explain to you what the  
24 risks of that procedure are. And in this case that's divided  
25 into two components. One is what is the risk of the procedure

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11:56:48 1     itself, and the second is what the risk of the specific  
2     device.

3             So that's an important conversation that needs to  
4     occur with the patient so that they can decide what risk do I  
11:56:59 5     want to take? Do I want to accept the risks that were  
6     explained to me and do I want to have this filter placed?

7             The only way for that -- for me to be able to relate  
8     to the patient what that risk is, is based on knowledge  
9     provided to me -- information provided to me by the device  
11:57:17 10    manufacturer, who knows about how their filter, their device,  
11    performs. And so using all that information together, I have  
12    a conversation with the patient to let them know what the  
13    risks are for having this procedure.

14            In this case, it was even more complicated because  
11:57:37 15    this was a brand-new device that had never -- for patient  
16    number one, this device had never been used in a human before,  
17    so we were really in a little bit of uncharted territory.

18    Q     So, for example, your patients that were going to be  
19    entering this study were being told there was a lack of  
11:57:53 20    experience with this precise device in humans.

21            Do you see where I am?

22    A     Yes. That's correct.

23    Q     And they were also being told: During the discussion with  
24    patients, I will clearly state that this filter has never, or  
11:58:16 25    seldom, following the first patient, been used in humans

## DIRECT EXAMINATION - MURRAY ASCH

11:58:21 1 before.

2 True?

3 A That's correct.

4 Q I will clearly offer the patient an alternative, paren, a  
11:58:27 5 currently approved permanent filter, end paren, with the  
6 understanding that there is no scientific knowledge of the  
7 results of having a filter in place for a long period of time.

8 Bard and NMT collaborated with you to write this  
9 consent form; true?

11:58:46 10 A That's correct.

11 Q In fact, that's true today, that there's really no  
12 scientific knowledge of the results of having a filter in  
13 place for a long period of time.

14 A That's correct.

11:58:56 15 Q By scientific knowledge, there's no -- what do you mean by  
16 that? So I don't get accused of leading.

17 A The only way to answer that question is there's also the  
18 fancy scientific study term we call long-term. "Long-term" is  
19 obvious. So we want to take the filter -- we would want to  
11:59:15 20 create a study where we, say, put filters into a number of  
21 patients and follow those patients for many, many years,  
22 long-term, and evaluate those patients rigorously, as opposed  
23 to everyday practice which doesn't involve follow up.

24 We want to follow patients up and look and see, does  
11:59:31 25 the filter fracture? Did it move? Does the filter occlude

## DIRECT EXAMINATION - MURRAY ASCH

11:59:36 1 and cause other symptoms or complications.

2 Only by doing a long-term study like that can we  
3 truly answer this question and be able to explain to patients  
4 what's going to happen. I'm going to put in a filter in you  
11:59:49 5 today, what's going to happen 15 years later with that filter  
6 in place.

7 MR. LOPEZ: I have one more page in this exhibit. I  
8 know it's past 12:00. Could I just finish this exhibit?

9 THE COURT: You may.

11:59:58 10 MR. LOPEZ: Let's go to the next page, please, under  
11 Follow-up.

12 First paragraph. Can you highlight that, Greg, and  
13 make it large for us.

14 BY MR. LOPEZ:

12:00:09 15 Q This was part -- is this part of the protocol for the  
16 study that you were going to apply to all patients, Dr. Asch?

17 A Yes. This is the protocol, yes.

18 Q Standard -- you were going to do routine follow-up  
19 abdominal radiographs to assess for filter migration obtained  
12:00:28 20 at 1 and 7 days and then at 30 and 60 days.

21 True?

22 A That was the plan for the study, yes.

23 Q And that additional follow-up will be performed on the  
24 physician's direction.

12:00:43 25 Is that how that reads?

## DIRECT EXAMINATION - MURRAY ASCH

12:00:45 1 A Yes.

2 MR. LOPEZ: And then the very last paragraph, which  
3 is actually a sentence. Could you highlight that, please.

4 BY MR. LOPEZ:

12:00:53 5 Q Also, part of the protocol was that any device-related  
6 adverse events or adverse events that are serious in nature  
7 will be reported immediately to the NMT Medical, Inc., and to  
8 Bard Canada, Inc. In addition these events will be reported  
9 to HBP, comma, Ottawa, immediately.

12:01:13 10 True?

11 A That's true.

12 Q We'll talk about those type of events after lunch.

13 THE COURT: All right.

14 We're going to break for lunch, ladies and gentlemen.

12:01:22 15 We'll plan to resume at 1 o'clock. We'll excuse you at this  
16 time.

17 (The jury exited the courtroom at 12:01.)

18 THE COURT: All right. Counsel, for your  
19 information, as of noon, plaintiffs have used three hours and  
12:01:59 20 44 minutes; defendants one hour and 42 minutes.

21 We'll see you at 1 o'clock.

22 MR. LOPEZ: Thank you, Your Honor.

23 (Recess taken at 12:02.)

24 (End of a.m. session transcript.)

25 \* \* \* \* \*



C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 16th day of March, 2018.

s/ Patricia Lyons, RMR, CRR  
Official Court Reporter